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Implementing Computer Assisted Cognitive Remediation
in a High Secure Forensic Psychiatric Setting

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Portfolio Thesis Abstract

Introduction

This thesis has two aims. The first was to systematically review the literature on the effect of computer assisted cognitive remediation (CACR) for schizophrenia on psychosocial functioning, with a focus on methodological quality and efficacy. The second aim was to evaluate the implementation of CACR in a high secure forensic setting.

Method

Database searches and hand searches returned 16 randomised controlled trials of CACR that included a functional outcome measure. These were reviewed against predefined quality criteria and effect sizes were calculated. In addition, an uncontrolled pre-post test design was used to evaluate the implementation of CACR in a high secure forensic hospital. Attrition rates, predictors of attrition, and participant feedback were evaluated, along with symptom and functional outcomes.

Results

The systematic review found a range of methodological limitations. Studies that did not share these limitations did not provide evidence that CACR improves psychosocial functioning. However, CACR may be effective in improving functional outcomes when delivered alongside interventions targeting functional skills. The experimental study found a high attrition rate; poor adherence to the treatment protocol; no clinical, risk or demographic factors to distinguish treatment completers from those dropping out during treatment; and few improvements to performance on treatment activities or functional outcome measures.

Conclusion

The systematic review indicates that more methodologically rigorous research is required. Future studies with a general psychiatric population should examine the effect of CACR delivered in conjunction with interventions that aim to develop functional skills. Motivational deficits may have undermined the outcomes of the experimental study and it will be important to ensure the delivery of CACR in forensic psychiatric settings is designed to incorporate strategies for enhancing motivation. In addition, using CACR to target functional outcomes may be inappropriate within a high secure forensic setting. The role of CACR as in managing risk and enhancing the outcomes of other interventions should be explored.

Word count: 13492 (excluding references and appendices)

Chapter 1: Systematic Review

This chapter contains a systematic review of the literature on the effect of computer assisted cognitive remediation for schizophrenia on psychosocial functioning, with a focus on methodological quality and efficacy. It was written according the author guidelines for the Journal of Psychiatric Research, which can be found in Appendix 1.1.

Word count: 5999

Systematic Review Abstract

Title: Improving Functional Outcomes in Schizophrenia with Computer Assisted Cognitive Remediation: A systematic review of effect sizes and methodology

Background: Computer assisted cognitive remediation therapy (CACR) has been developed in response to the recognition that problems with psychosocial functioning in people diagnosed with schizophrenia are related to deficits in cognitive functioning. A previous review suggested CACR is effective in improving cognitive outcomes, however the review did not cover functional outcomes or review methodological quality. This paper addresses these gaps in the literature by systematically reviewing randomised controlled trials of CACR that include a functional outcome measure, focusing on methodological quality and efficacy in improving functioning.

Method: Electronic databases (Medline; PsychINFO; Embase) were searched for articles on schizophrenia, and both computer and cognitive remediation terms. Cohen's d was used to evaluate efficacy and an adapted version of the SIGN-50 quality assessment tool was used to assess methodological quality.

Results: 511 papers were identified, with 22 articles covering 16 studies remaining after exclusion criteria. A range of significant methodological weaknesses were found and almost 50% of effect sizes were small or negligible. Methodologically stronger studies appeared to return smaller or negligible effect sizes. Despite these issues, some evidence was found to support the suggestion that CACR may improve functional outcomes when delivered in conjunction with an intervention targeting the development of functional skills.

Conclusions: There is little evidence to support the use of CACR as a stand-alone intervention. Methodologically rigorous RCTs are required that explore the efficacy of

CACR when delivered in conjunction with interventions targeting the skills underpinning real-world functioning.

Highlights:

- A range of significant methodological weaknesses were found
- Almost 50% of effect sizes were small or negligible
- Methodologically stronger studies appeared to return smaller or negligible effect sizes
- CACR may improve functional outcomes when delivered in conjunction with an intervention targeting the development of functional skills.

Keywords: Computer; cognitive; remediation; rehabilitation; schizophrenia; functioning

Introduction

Cognitive impairment has been referred to as a “core feature” of schizophrenia (Minzenberg & Carter, 2012). Up to 90% of those diagnosed are thought to have clinically significant deficits in at least one domain of cognitive functioning (Palmer et al., 1997), with deficits persisting regardless of the presence or absence of other symptoms of schizophrenia (Nieuwenstein et al., 2001).

Schizophrenia has also been associated with significant and disabling impairments across a range of functional domains, including interpersonal and occupational functioning, daily living skills, and the ability to benefit from intervention programmes (Green et al., 2000). The most robust predictor of functional impairments has been identified as cognitive deficits (Green et al., 2000), which appear to have more influence on functional difficulties than positive or negative symptoms (Kurtz, et al., 2005).

Studies suggest that the relationship between cognitive functioning and real-world outcomes is mediated by ‘functional capacity’ (Harvey & Strassing, 2012). Functional capacity is a construct encompassing the skills necessary to perform the acts associated with day-to-day functioning (Harvey & Strassing, 2012) and may be as predictive of real-world outcomes as cognitive functioning (Bowie et al., 2008). There appears to be a significant overlap between functional capacity and cognitive functioning (Leifker, et al., 2011), which suggests that the successful acquisition of functional skills is likely to be influenced by cognitive ability.

Cognitive Remediation

The recognition of the link between cognitive deficits and functional impairments in people diagnosed with schizophrenia has led to the development of cognitive remediation (CR), a group of psychological interventions “targeting cognitive deficit (attention, memory, executive function, social cognition or meta cognition) using scientific principles of learning with the ultimate goal of improving functional outcomes” (McGurk et al., 2013). CR often involves repeating numerous trials of tasks designed to challenge particular areas of cognitive processing, and can also involve developing compensatory strategies to bypass the effects of cognitive dysfunction (Medalia & Choi, 2009). Many CR interventions are delivered via computers (computer assisted cognitive remediation; CACR), which affords a

range of benefits over pencil-and-paper approaches, including the automatic adjustment of difficulty in response to performance and the reduction in costs due to fewer hours of therapist involvement (Grynszpan et al., 2011).

Effectiveness of Cognitive Remediation

Two relatively recent meta-analyses have looked at the efficacy of CR. The first, by Wykes et al. (2011) encompassed randomised controlled trials (RCTs) of all forms of CR and found a moderate effect on neuropsychological functioning (Cohen's d effect size; $ES=0.45$) and a moderate effect on psychosocial functioning ($ES=0.42$). The effect sizes for functional outcomes were larger when CR was delivered in conjunction with an intervention facilitating the generalisation of cognitive gains to daily functioning (Wykes et al., 2011). Concurrent functional interventions of this type have been defined as additional treatment components that "teach compensatory strategies and/or explicitly link cognitive gains to functional skills and real-world situations" (Medalia and Saperstein, 2013).

The second meta-analysis focused specifically on CACR (Grynszpan et al., 2011). Although a moderate effect was found on neuropsychological functioning ($ES=0.38$), too few studies employed an appropriate functional outcome measure for this to be included in analyses (Grynszpan et al., 2011). The frequent omission of functional outcome measures in CR studies has been acknowledged as a significant weakness in the evidence base (Medalia & Saperstein, 2013), however since the publication of Grynszpan et al. (2011) a growing number of RCTs have been published with functional outcomes as a co-primary measure. Steps have also been taken to identify the best available measures of real-world functioning (the 'VALERO' study; Leifker et al., 2011) and functional capacity (MATRICS-VIM; Green et al., 2011) to encourage a consistent approach to measuring functioning and facilitate comparisons between studies.

Although the evidence for CACR appears to be promising, significant concerns have been raised about the methodological quality of CR research, leading to recommendations that better quality studies are required before CR can be adopted in clinical practice (NICE, 2009). Advocates for CR have dismissed concerns about methodological weaknesses, with Wykes et al. (2011) pointing out that methodological quality did not influence effect sizes in their meta-analysis, leading to the suggestion that the field should now move on from

efficacy studies and begin looking at implementation research. However, it should be noted that the method used by Wykes et al. (2011) to explore the relationship between methodological quality and efficacy in meta-analyses has been challenged (Herbison, 2006).

Rationale for the Review

The literature suggests that CACR is associated with improvements in neuropsychological functioning and potentially offers a range of benefits over non-computer based CR approaches (Grynszpan et al., 2011). However, a number of gaps remain in the literature, including a review of the efficacy of CACR in improving functional outcomes and a review of the methodological quality of CACR studies, both of which were omitted in the meta-analysis by Grynszpan et al. (2011).

Objectives

This study aimed to evaluate the evidence for the effectiveness of CACR in improving functional outcomes for people diagnosed with schizophrenia. It also aimed to evaluate the methodological rigour of studies in this area.

To achieve this, a review was carried out of randomised controlled trials that assessed the efficacy of CACR in improving functional outcomes in individuals with a diagnosis of schizophrenia or schizoaffective disorder, compared to treatment as usual; a waiting list-control; or an active control condition.

Method

The review followed the processes outlined by the Centre for Reviews and Dissemination (2009) and was guided by The PRISMA Statement for Reporting Systematic Reviews and Meta-Analyses of Studies That Evaluate Health Care Interventions (Liberati et al., 2009).

Eligibility of Studies

Studies were evaluated against the following criteria:

Types of publications: Studies were included if they were published in a peer reviewed, English language journal. Unpublished dissertations and conference abstracts were excluded.

Types of Studies: Studies were included if they were RCTs that employed a parallel control condition, including passive control conditions (treatment as usual, TAU; waiting list controls) or active control conditions that did not explicitly aim to improve cognitive functioning (e.g. a computer games control condition). Studies were also required to state that allocation to treatment and control conditions was randomised, with the appropriateness of the randomisation method forming part of the quality review.

Types of Participants: Participants could be of any age, with a diagnosis of schizophrenia or schizoaffective disorder.

Types of Intervention: Studies were required to have a treatment condition that used software-based cognitive training delivered via a computer, which aims to remediate cognitive deficits. Studies were included if the treatment condition involved CACR alone or if it involved a non-computer based element (e.g. guidance from a therapist; a concurrent group).

Types of Outcome Measures: Studies were required to use one or more validated rating scale identified by the paper authors as measuring aspects of psychosocial functioning.

Identification of Studies

Studies were initially identified by searching the electronic databases Medline, PsychINFO and Embase. Searches were conducted on 20th October 2013 with no date restrictions imposed. The search involved the same terms used by Grynszpan et al. (2011) (“computer” or “computerized”, “cognitive”, “rehabilitation” or “remediation” or “training”, and “schizophrenia”). Duplicate studies were removed by the search engine during the search process.

The list of titles and abstracts produced by the above process were then reviewed for eligibility. This primarily involved applying the ‘Types of publications’ criteria outlined above, however studies were also removed if they unambiguously breached other criteria (e.g. a clear indication that the study used a non-RCT design, such as a case study approach). Duplicate papers that were missed by the search engine were also removed. Full-text versions of the remaining studies were then obtained and reviewed against all of the eligibility criteria.

The reference lists of eligible studies were then searched, along with the contents of the journals containing the eligible studies. Full-text versions of any studies making reference to cognitive remediation were then reviewed and any meeting the eligibility criteria above were included in the review.

Data Extraction

From all papers involved in each individual study, the following was extracted:

1. Methodological characteristics of the study (research question; method of randomisation; method of concealment of randomisation; extent of blinding; single centre or multi-centre) and the type of outcome measure used (including pre and post treatment means and standard deviations for both the treatment and control groups).

2. Demographic characteristics of participants (including age, gender, education level), the study inclusion and exclusion criteria, the setting participants were recruited from (i.e. inpatient or outpatient) and baseline imbalances between treatment and control groups.

3. Treatment characteristics (a description of the intervention; the frequency of treatment sessions; the duration of treatment) and characteristics of the control condition.

4. Attrition rates.

A copy of the data extraction form can be found in Appendix 1.2.

Quality Assessment

To evaluate the studies included in the review, an adapted version of the 10-item quality assessment tool developed by The Scottish Intercollegiate Guidelines Network for randomised controlled trials was used (Scottish Intercollegiate Guidelines Network, 2008).

Adaptations to the SIGN assessment tool

Previous research has indicated that there is likely to be a delay between improvements to cognitive functioning and the generalisation of these gains to real-world functioning (Green et al., 2004) which highlights the importance of ensuring that adequate follow-up assessments are included in CACR studies to capture any change in functional outcomes. It has also been suggested that many CR studies fail to include an adequate control group (Boot et al., 2013). As a result, these two factors were included alongside the original 10 items from the SIGN assessment tool.

Operationalising the assessment tool

The 12 quality criteria were rated as 'well covered = 2, adequately addressed = 1, poorly addressed/addressed/not reported/not applicable = 0. Lower scores on the quality tool either represented an increased risk of bias resulting from the item, or a lack of information to adequately rate the item.

Scores were totalled across the quality criteria and an overall percentage score given. Full details of the scoring system can be found in Appendix 1.3. Where relevant, the scoring of quality criteria focused on aspects of the study specific to functional outcomes (e.g. blinding was scored in relation to the assessment of functional outcomes, regardless of whether assessments of neuropsychological or symptom outcomes were blinded).

Scoring the quality assessment tool

All studies were rated by the author, while 50% were also rated by an individual independent of the study. Inter-rater agreement was 'good' (Kappa=0.70; Cohen, 1960) according to standards set out by Landis and Koch (1977) . Differences between raters were discussed until a consensus was reached, with scores amended accordingly.

It should be noted that one item from the quality criteria, 'Results Comparable Across Sites', is only applicable to multi-centre studies. As such, this item was omitted for single-centre studies, with the overall score adjusted accordingly.

Data Analysis

Effect sizes were calculated using Cohen's d (Cohen, 1992), based on the means and standard deviations published in the paper for each functional outcome measure or the subscale of each measure at each time point (i.e. post-treatment, follow-up). For the calculation of effect sizes, the control group was considered to be the treatment as usual group, the waiting list control group, a computer games control condition, or any other another active control condition not designed to target neuropsychological functioning.

Results

Overview

The CONSORT diagram in Figure 1 provides an account of the search process and Table 1 provides details of each study included in the review. A list of papers that were subject to a full text review but were excluded from the study can be found in Appendix 1.4, along with reasons for their exclusion.

Study characteristics

22 different reports of 16 studies, reporting data on 1061 participants, met the inclusion criteria. Papers were published between the years 2004 and 2013. Eight studies recruited from outpatient settings, three from inpatient settings, two from both, while three did not specify. Studies were carried out in eight different countries. The average sample size was approximately 66 (mean=66.31, SD=23.47).

Participant characteristics

Participants were in their early 40s (n=16, mean age=40.59, SD=12.19), predominately male (n=14, mean=71.39%, SD=12.01), with 11 to 12 years of education (n=13, mean years=11.71, SD=1.32).

Assessment characteristics

Across the studies reviewed, 17 different functional outcome measures were used. The modal number of measures used in each study was one, however three studies employed three different functional outcome measures. Two studies combined multiple outcomes into a single composite measure. A description of the outcomes measures used can be found in Appendix 1.5.

Figure 1: CONSORT diagram

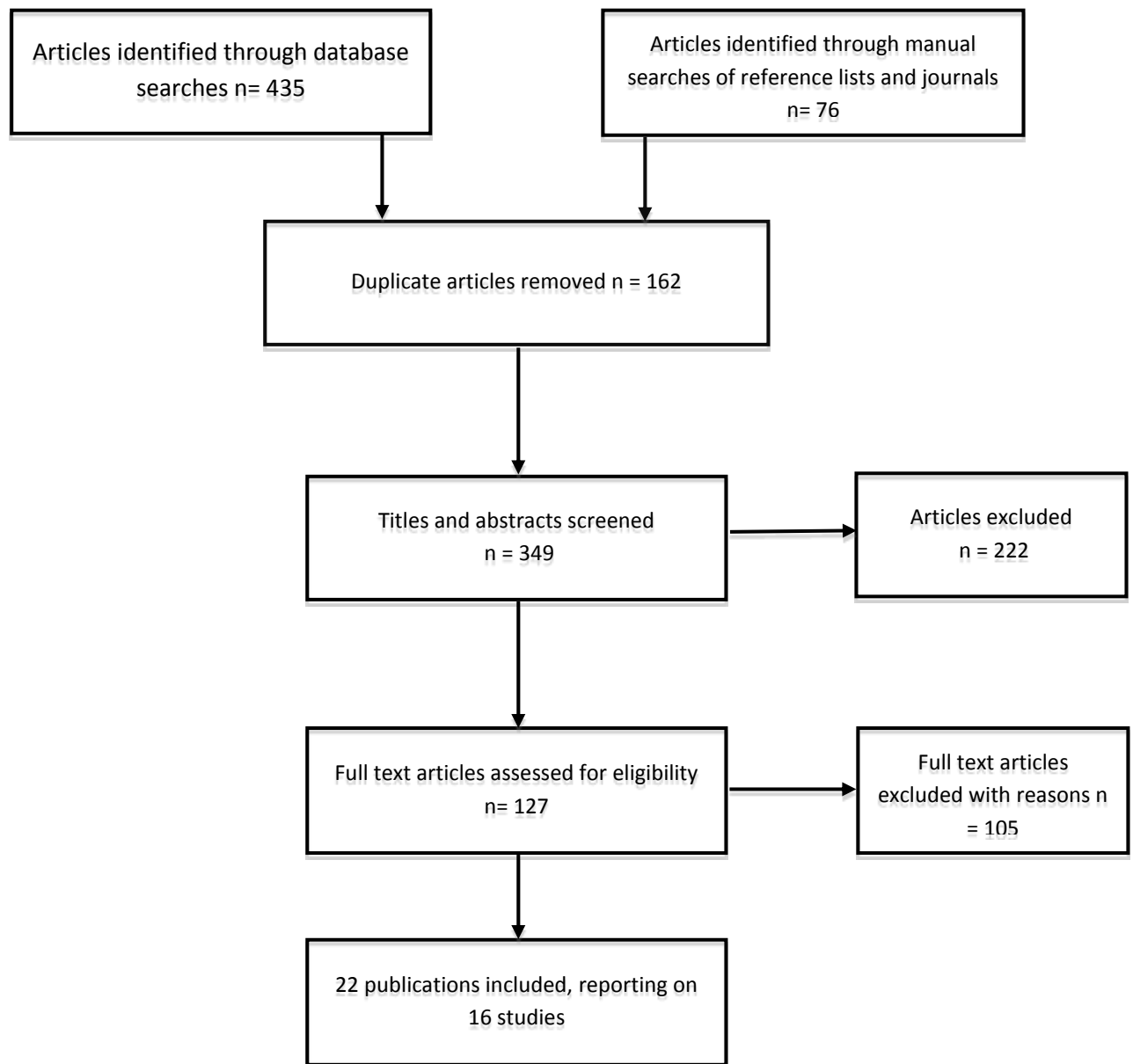


Table 1: Summary of included studies

Study*	Sample Characteristics (Setting; country; mean age in years; mean years of education; % male)	Treatment Group(s) (Name of CACR treatment; n)	Additional Treatment Alongside CACR	Treatment Delivered (Weekly Frequency; Total Treatment Hours)	Control Group (active/passive control, n)	Follow-up (months)	Outcome measure and Effect Size** (Follow-up ES in parentheses)
Dickinson et al., 2010	Unclear; USA; 46.6; NR; 69.8%	Computer Assisted Cognitive Remediation for Schizophrenia; n=34	None	15 weeks; 3 x 1 hour; 36 sessions (target) 32.2 sessions (mean actual)	Computer-games (active, n=27)	3 months	UPSA=-0.30 (0.44) MASC=0.19 (-0.05)
Bowie et al., 2012	Outpatient; USA/Canada; 40.6; 13.1; NR	Thinking Skills for Work Programme (incorporates Cogpack, PSSCogRehab and Scientific Brain Training) n=36	None	12 weeks; 2 hours per week; 24 hours (target) 20.88 hours (mean actual)	Functional adaptation skills training (active, n=35)	12 weeks	Outcome data not reported (Measures used: SSA; SLOF; AC)
Fisher et al., 2009; Fisher et al., 2010	Outpatient; USA; 44.0; 13.4; NR	Posit Science Brain Fitness Auditory Training; n=22	None	10-20 weeks; 5 x 1 hour; 50 or 100 hours (target); 72.7 hours (mean actual)	Computer-games (active, n=10)	6 months	QLS=(0.23)***
Eack et al., 2009; Eack et al., 2010;	Inpatient and outpatient; USA; 25.9;	Cognitive Enhancement Therapy; n=31	Social cognitive group sessions	2 years; 1 x 1 hour; 60 hours (approx. target)	Enriched supportive therapy (active, n=27)	1 year	SA=1.02 (0.53)

Eack et al., 2011	NR; 69.0%						
Cavallaro et al., 2009; Poletti et al., 2010	Outpatient; Italy; 33.6; 11.7; 60.0%	Cogpack; n=50	Group-based psychiatric rehabilitation targeting "social abilities, work and autonomy"	12 weeks; 3 x 1 hour; 36 hours (target)	Computer-aided non-domain specific activity (active, n=36)	3, 6 and 12 months	QLS=0.29 (0.41; 0.56; 0.79)
D'Souza et al., 2012	Unclear; India/USA 37.19; 12.68; 75%	1. CogRehab plus d-serine n=24 2. CogRehab plus placebo d-serine n=27	None	12 weeks; 5 hours over 2-3 days; 60 hours (target)	<u>Control 1</u> Video watching plus d-serine (active, n=27) <u>Control 2</u> Video watching plus placebo d-serine (active, n=26)	24 weeks	<u>Control 1</u> SSA=-0.05 (-0.13) UPSA=0.03 (0.13) QLS=-0.15 (-0.04) <u>Control 2</u> SSA=0.54 (0.40) UPSA=-0.07 (-0.07) QLS=0.15 (0.01)
Bucci et al., 2013	Outpatient; Italy; 38.2; 10.6; 81.0%	Rehacom; n=25	None	6 months; 2 x 1 hour; 48 hours	Social Skills Individualised Training (active, n=33)	6 months	QLS-IntRel=0.45 (0.38) QLS-InsRol=-0.36 (-1.20)

Vita et al., 2011; Vita et al., 2013	Outpatient; Italy; 39.0; 10.5; 69.1%	Cogpack; n=30		None	24 weeks; 2 x 45 mins; 31.5 hours (actual mean)	Non-cognitive psychosocial intervention (active, n=28)	None	GAF=0.32 HoNOS=0.59
Keefe et al., 2012	Outpatient; USA; 37.0; 13.5; 73.6%	Posit Science Brain Fitness Auditory Training; n=25		"Bridging groups" to extend skills to everyday tasks	8-12 weeks; 5 hours per week; 40 hours (target)	Computer games and health lifestyles group (active, n=22)	None	UPSA=-0.15 SLOF=0.23
Galderisi et al., 2010	Outpatient; Italy; 39.8; 10.0; 66.7%	RehaCom; n=26		Social skills training groups	6 months; 2 x 1 hour; 48 hours	Structured leisure activities (active, n=23)	None	AD=0.54
Garrido et al., 2013	Inpatient; Spain; 33.30; 9.85; 73.1%	Gexy and copy programmes, and Bracy Soft Tools; n=38		None	6 months; 2 x 60 mins; 48 hours	Video watching (active, n=29)	None	QLS=0.67
Hodge et al., 2010	Inpatient and outpatient; Australia; 31.3; 11.0; 60%	Neuropsychological Educational Remediation; n=22	Approach to	None	10-15 weeks; 2 x 1 hour; 30 sessions (maximum target)	Wait-list control (passive, n=18)	4 months	Outcome data not reported (Measures used: SOFAS; LSP; WHOQOL-Bref)
Lee, 2013	Inpatient; South Korea; 43.5;	Cogtrainer; n=30		None	3 months; 1 or 2 x 1 hour; 20 hours (target)	Rehabilitation programme (active, n=30)	None	WBI-WQ=1.40 WBI-WH=1.85 WBI-C=0.01

	12.8; 55.0%									WBI-SS=0.09 WBI-SP= -0.34
Byrne et al., 2013	Inpatient; China; 46.5; 10.8 100%	Computer Programme; n=14	Drill	Training	None	4-6 weeks; 2 to 3 x 30 to 60 mins (at least 12 sessions)	Treatment as usual (passive, n=17)	None		PSP=0.78
d' Amato et al., 2011	Unclear; France; 32.8; 12.3; 75.3%	RehaCom; n=39			None	7 weeks; 2 x 2 hours; 28 hours	Treatment as usual (passive, n=38)	None		SQoL=0.25 EAS=-0.17
Hogarty et al., 2004 Hogarty et al., 2006	Outpatient, USA; 37.3; NR; 59.0%	Cognitive Therapy; n=67	Enhancement	Social cognitive group sessions	2 years; NR; 75 hours (approx. target)	Enriched supportive therapy (active, n=54)		1 year		SA=0.37 (0.47)

*Where study data is across multiple papers, the earliest published paper is used to identify the study in the body of the text; **Abbreviations: AC=Adaptive composite; AD=The Interview for the Assessment of Disability; EAS=Social Autonomy Scale; GAF=Global Assessment of Functioning; HONOS=Health of the Nation Outcome Scale; LSP=Life Skills Profile; MASC=Maryland Assessment of Social Competence; PSP=Personal and Social Performance Scale; QLS=Quality of life scale; SA=Social Adjustment; SLOF=Specific Levels of Functioning Scale; SOFAS=Social and Occupational Functioning Scale; SQoL=Schizophrenia Quality of Life; SSA=Social Skills Performance Assessment; UPSA=University of California San Diego Performance-Based Skills Assessment Battery; WBI=Work-Behaviour Inventory; WHOQOL-Bref=World Health Organization Quality of Life-BREF; ***Post-treatment data unavailable

Intervention characteristics

11 different CACR programmes were used. The most frequently used CACR interventions were Rehacom and Cogpack which were each used by three studies. Some studies used elements from multiple CACR interventions (Bowie et al., 2012; Garrido et al., 2013).

Variability in the reporting of the total number of hours of treatment delivered, as well as the frequency of sessions, precludes the calculation of averages across studies, however details of these aspects of treatment can be found in Table 1 for each study.

Methodological Quality

Table 2 provides a breakdown of the quality ratings for the 16 studies included in the review. Significant areas of methodological quality are discussed below.

Attrition

Scores for attrition rates in Table 2 reflect both the proportion who dropped out during treatment, as well as approximate equivalence in attrition between control and experimental groups. Two studies failed to report attrition rates (Hodge et al., 2010; d'Amato et al., 2011), while three others scored '1' or '0' due to high overall attrition rates (Eack et al., 2009; Fisher et al., 2009; Byrne et al., 2013). The relatively high attrition rate in the Eack et al. (2009) study perhaps reflects that the intervention took place over a longer period than in other studies (two years). Byrne et al. (2013) had the highest level of attrition of any of the studies and also had large differences in attrition between groups. It should be noted that this was one of only two studies to solely recruit inpatients and was also the only study to give comprehensive details of the reasons for attrition. Two other groups scored lower due to differences in attrition between groups (D'Souza et al., 2012; Garrido et al., 2013), which may in part reflect the qualitative differences between the experimental and control tasks.

Randomisation/Concealment

While no studies appeared to use an inappropriate method of randomisation, the majority simply stated that participants had been randomised into groups, with only six providing a clear enough description to judge the appropriateness of the procedure. Similarly, efforts to conceal the randomisation process from researchers were only mentioned in a minority of studies. None of these gave a clear description of the process used and all were therefore scored as '1'.

Outcomes measures

All measures were validated rating scales as this was an inclusion criteria for the study, however those scoring '1' represents the fact that these were not validated for use with a schizophrenia population. Nine studies used measures recommended either by the VALERO (Leifker et al., 2011) or the MATRICS-VIM studies (Green et al., 2011) (UPSA, QLS, LSP, SLOF).

Control group and blinding

Only four studies scored '2' for using a computer games control condition. All four attempted to match other aspects of the control condition to those of the experimental group, such as the frequency of sessions and contact with therapists. One of the studies using a computer games control took steps to ensure that both assessors and participants were blind to the treatment condition (Dickinson et al., 2010); two blinded assessors only (Fisher et al., 2009; Keefe et al., 2012); while one ensured only participants were blinded (Cavallaro et al., 2009).

Table 2: Summary of quality ratings

Authors	Attrition	Groups similar at start	Clear research Question	Randomised	Concealment	Blinding	Treatment only difference	Sufficient follow-up	Adequate control condition	Standardised outcome measures	Intention to treat	Results comparable across sites	Total Score	Percentage
Dickinson et al., 2010	2	2	2	2	0	2	0	1	2	2	0	2	17	70.83%
Bowie et al., 2012	2	2	2	1	0	0	2	1	1	2	1	2	16	66.67%
Fisher et al., 2009	1	2	1	1	1	1	1	2	2	2	0	2	16	66.67%
Eack et al., 2009	1	2	2	2	0	0	1	2	1	2	2	0	15	62.50%
Cavallaro et al., 2009	2	2	1	1	0	1	1	2	2	2	0	0	14	58.33%
D'Souza et al., 2012	1	2	1	2	0	1	1	1	1	1	0	2	13	54.17%
Bucci et al., 2013	2	2	0	1	1	1	0	2	1	2	0	0	12	50.00%
Vita et al., 2011	2	2	1	1	1	0	0	0	1	2	2	0	12	50.00%
Keefe et al., 2012	2	2	1	1	0	1	0	0	2	2	0	0	11	45.83%
Galderisi et al., 2010	2	2	2	1	1	1	0	0	1	1	0	0	11	45.83%
Garrido et al., 2013	1	0	2	2	1	1	0	0	1	2	0	Omit	10	45.45%
Hodge et al., 2010	0	2	2	2	1	0	0	1	0	2	0	0	10	41.67 %
Lee, 2013	2	2	1	1	0	0	1	0	0	2	0	Omit	9	40.91%
Byrne et al., 2013	0	2	2	2	1	0	0	0	0	2	0	Omit	9	40.91%
d' Amato et al., 2011	0	2	2	1	0	1	0	0	0	2	0	0	8	33.33%
Hogarty et al., 2004	2	0	0	1	0	0	0	2	1	2	0	0	8	33.33%

Key: 2=Well covered; 1=Adequately addressed; 0=Poorly addressed/not addressed/not reported; Omit=item not applicable

Table 1 includes a description of the control conditions for the remaining studies. Eight studies scored '1' and used a variety of active control conditions, such as watching videos. The extent to which these active conditions control for non-specific aspects of treatment will vary, however it should be noted that a number attempted to match some aspects of the experimental condition, such as therapist contact.

Other treatment

Six papers attempted to account for other treatments that could create imbalances between groups. Five of these papers scored a '1' as the description only accounted for changes to medication regimes during treatment. Bowie et al. (2012) was the only paper to score '2' due to giving a clear account of ongoing treatment and assurances that this excluded anything that would be likely to affect cognitive or functional outcomes.

Follow-up

Almost half the studies failed to include any follow-up. Of those that did, only five scored '2' for following-up participants at 6 months or beyond. Only one paper included follow-ups at multiple time-points to track developments in post-treatment effects (Cavallaro et al., 2009).

Intention-to-treat analyses

Only three studies included an ITTA, with one only scoring '1' for failing to explain the procedure used to address missing data (Bowie et al., 2012). One paper used a "modified ITTA" (Dickinson et al., 2010). Although this may have retained some of the methodological benefits of an ITTA, it was scored as a '0' for violating the ITTA principles by failing to include in the analysis all patients randomised.

Multi-centre

The majority of studies were classed as multi-centre as participants were recruited across multiple locations, however it was often not reported if treatment and assessments also took place across multiple locations. Only five studies accounted for potential differences between sites in their analyses.

Efficacy

The overall effect of CACR in relation to functional outcomes is covered below, before efficacy is discussed in relation to a range of methodological issues.

Overall

Based on conventions for the categorisation of effect sizes (Cohen, 1992), 92.31% of studies reporting post-treatment data had at least one outcome measure demonstrating a small effect size ($d \geq 0.2$) post-treatment, 53.85% had at least 1 medium effect size ($d \geq 0.5$), and 15.38% had at least 1 large effect size ($d \geq 0.8$). Looking at each of the post-treatment effect sizes in Table 1, 22.22% are small, 18.53% are medium, and 11.11% are large. Almost half of the calculated effect sizes (48.15%) do not meet the criteria to be classed as “small”.

Two studies did not publish post-treatment means and standard deviations for functional measures and therefore no effect size was calculated. One study (Fisher et al., 2009) only provided means and standard deviations at the follow-up stage, therefore there is no post-treatment effect size.

Control group and blinding

For well controlled studies (i.e. those scoring ‘2’), post-treatment effect sizes ranged from -0.30 to 0.29. For the only well-controlled study that used a double blind procedure

(Dickinson et al., 2010), all effect sizes failed to reach the threshold to be considered 'small'. Despite this, two well-controlled studies (Dickinson et al., 2010; Cavallaro et al., 2009) found increased effect sizes at follow-up, with Cavallaro et al. (2009) finding a progressive increase in effect sizes at each follow-up stage. This may indicate that it takes time for the cognitive benefits of treatment to generalise to functional outcomes, however this idea is undermined by the failure of Dickinson et al. (2010) to find any benefits in cognitive functioning.

Follow-up

In total, five studies reassessed participants six months or longer after treatment ended and found small to medium effects at the follow-up stage. It should be noted that two of these studies (Hogarty et al., 2004; and Bucci et al., 2013) were among the lowest rated in terms of overall quality. However, three were among the highest rated overall for quality (Fisher et al., 2009; Cavallaro et al., 2009; Eack et al., 2009). The two that found a medium effect size at follow-up were also the studies that involved a concurrent intervention targeting functional outcomes (Cavallaro et al., 2009; Eack et al., 2009), which may help to account for the durability of these effects.

Concurrent functional intervention

Five studies included a functional intervention alongside CACR (Eack et al., 2009; Cavallaro et al., 2009; Keefe et al., 2012; Galderisi et al., 2010; Hogarty et al., 2004). Post-treatment effect sizes ranged from -0.15 to 1.02, and all studies found at least a small effect post-treatment, with the exception of Keefe et al. (2012). The largest effect size was from Eack et al. (2009), whose functional intervention appears to be the most comprehensive, lasting 2 years. These results lend some tentative weight to the idea that the generalisation of cognitive improvements to functional outcomes is best achieved when CACR is delivered with a functional intervention. It was not possible to calculate ES for Bowie et al. (2012), however their results provide additional support to this argument. The study involved three treatment conditions: CACR only; a functional intervention only; CACR combined with

the functional intervention. CACR was only associated with improved functioning when delivered in combination with the functional intervention, which also outperformed the functional intervention on its own (Bowie et al., 2012).

Multi-centre

The three single centre studies mostly returned medium to large effect sizes (Garrido et al., 2013; Lee, 2013; Byrne et al., 2013), reflecting previous research that suggests single-centre approaches return higher effects than multi-centre studies (Kahan, 2014). However it should also be noted that these studies were also among the lowest rated overall for quality.

Outcome measures

Of the recommended outcome measures used within the studies reviewed, effect sizes were available for both the UPSA and QLS (see Table 1). No studies using the UPSA found even a small post-treatment effect, however none employed a concurrent functional intervention. With regards to the QLS, Garrido et al. (2013) and Cavallaro et al. (2009) found medium effect sizes at post-treatment or follow-up with Bucci et al. (2013) also finding small to medium effect sizes on two QLS subscales, however these were smaller at follow-up.

Discussion

Main Findings

This systematic review aimed to look at the methodological quality and efficacy of CACR in improving functional outcomes. A range of significant methodological weaknesses were identified, while the effect sizes were mostly small or negligible. Although it was only possible to take a descriptive look at the relationship between methodology and efficacy, it would appear that methodologically stronger studies tended to return small or negligible effect sizes. Despite these issues, some evidence was found to support the suggestion that CACR may improve functional outcomes when delivered in conjunction with an intervention targeting the generalisation of cognitive gains to day-to-day functioning.

Do the methodological limitations matter?

Past concerns about the methodological quality of CR studies led to the intervention not being recommended in clinical guidelines (NICE, 2009). Similarly, the meta-analysis of CR by (Wykes et al., 2011) included a measure of methodological quality and found that less than a third of studies reached the threshold to be considered “adequate” (Wykes, et al. 2007). Despite this, Wykes et al. (2011) did not find any relationship between scores on the quality measure and effect sizes, leading them to conclude that methodological limitations do not inflate effect sizes. As an explanation, they suggest that inadequate blinding procedures are less concerning for CR RCTs in comparison to other psychological therapies such as CBT for psychosis, as cognitive outcome measures are less prone to bias compared to symptom outcome measures.

The dismissal of methodological problems in CR by Wykes et al. (2011) can be challenged on a number of counts. Cognitive measures may be designed to reduce bias, however an element of clinical judgement is still involved and these assessments may be more prone to bias than Wykes et al. (2011) imply. Regardless, many measures of functioning rely heavily on clinical judgement, leaving blinding as an important design feature of future RCTs of CACR. More fundamentally, the use of scores from a quality scale to look at the effect of

quality on outcomes has been criticised, principally because such measures can omit significant aspects of methodology, and different quality measures often give different results (Herbison et al., 2006). As a result, the methodological limitations of CACR and CR studies cannot be so easily dismissed.

Efficacy of CACR

The lack of functional improvements found in this study, taken in conjunction with Grynszpan et al. (2011)'s findings of improvements to cognitive outcomes following CACR, suggest that while cognitive deficits may *predict* deficits in functioning, cognitive improvements do not automatically lead to improvements in functioning. It seems likely that the generalisation of cognitive improvements to day-to-day functioning requires the mediation of a functional intervention that facilitates practicing the underlying skills. This would reflect the findings of this review, as well as those of the meta-analysis by (Wykes et al., 2011), that the addition of a functional intervention alongside CACR appears to be associated with functional improvements. The study by Bowie et al., (2012) would further support this idea, with their finding that the benefits of CACR generalised to functional outcomes when paired with a functional skills training. This suggests that CACR should be reconceptualised as a 'booster' for functional interventions, rather than a 'stand-alone' therapy.

Recommendations for future research

Given the limitations found in the research covered in this review, little value can be added by further efficacy studies that fail to use rigorous methodological approaches. The design of future RCTs should pay particular attention to the related issues of blinding and control groups. In comparison to other psychological interventions, the nature of CACR creates greater scope for the development of control groups that closely resemble intervention conditions (Boot et al., 2013), which in turn facilitates the possibility of blinding both participants and assessors.

The review would also suggest that there is limited benefit to further studies of CACR as a stand-alone intervention. Although the findings suggest that a concurrent intervention is required to generalise cognitive gains, there remain few methodologically sound studies to support this. Further research is required, and may benefit from broadly following the approach of Bowie et al. (2012) to explore the relative contributions of cognitive and functional treatment elements. Also, participants should be followed up at least 6 months after the end of therapy, given the potential time-lag between therapy and skill acquisition (Green et al, 2004).

More broadly, future meta-analyses of the efficacy of CACR should explore the effect of methodological weaknesses on effect sizes, otherwise doubts will remain over the effectiveness of CACR. It will be important that this involves a different method to that used by Wykes et al. (2011).

Recommendations for clinical practice

The results of this review would indicate that there is little evidence to support the implementation of CACR as a stand-alone intervention to improve functional outcomes. In addition, there remains only preliminary evidence that CACR combined with a functional skills intervention has any impact on functional capacity of real-world functioning. As such, further research is required before CACR can be recommended for clinical practice, if the goal of treatment is to improve functioning.

Strengths of the Review

The review fills a significant gap in the literature by systematically reviewing the evidence base for the efficacy of CACR in addressing functional deficits. It also provides an evaluation of CACR methodology that is not present in the published literature. The quality evaluations demonstrated good inter-rater reliability. The review also provides a broad coverage of the literature by implementing few limitations on outcome measures, CACR treatments, and participant characteristics.

Weaknesses of the Review

The review only covers English language publications due to resource limitations restricting the ability to translate papers. Quality ratings have been made on the basis of trial reports and authors have not been contacted; therefore some of the ratings may reflect reporting omissions rather than methodological limitations. The quantitative approach used to assess the quality of studies has been criticised (Herbison et al., 2006) and it is possible that this gives an inaccurate assessment of relative methodological strength. The criteria used to rate specific aspects of methodology may inadvertently mask relative strengths or weaknesses (e.g. giving the same rating to “modified” ITTA as to those that used no ITTA).

The review aimed to address a gap in the literature, with search terms and eligibility criteria chosen to provide continuity between this review and the meta-analysis by Grynszpan et al. (2011). As a consequence, schizoaffective disorder was not included as a search term despite studies being included if participants had this diagnosis. This mismatch between search terms and inclusion criteria creates the possibility that studies meeting eligibility criteria may not have been picked up in the original search.

Conclusion

Past criticisms of the methodological quality of CR interventions continue to be valid in relation to the subset of CACR studies that include a functional outcome measure. Although there is little high quality evidence to indicate stand-alone CACR is effective in improving functioning, there is some promise that it may act as a ‘booster’ treatment for interventions that aim to develop the skills underpinning real-world functioning. Nonetheless, further research is required before CACR can be recommended for clinical practice.

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Preparation

Article structure

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Appendix 1.2 – Data Extraction Form

Data extraction form

Study ID (<i>surname of first author from the first full report of study, and year first full report of study was published e.g. Smith 2001</i>)	
Report ID(s)	
Notes	

General Information

Date form completed (<i>dd/mm/yyyy</i>)	
Reference citation(s)	
Notes:	

Study eligibility

Study Characteristics	Eligibility criteria (<i>Insert inclusion criteria for each characteristic as defined in the Protocol</i>)	Eligibility criteria met? Yes No Unclear	
Type of study	Randomised Controlled Trial	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
Participants	Over 18	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
	Diagnosis schizophrenia/schizoaffective disorder (in both treatment group and experimental group)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
Types of intervention	Computer based CRT <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
Types of comparison (<i>i.e. control group, other treatment</i>)	Eligible: CACR vs TAU <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
	CACR vs active control <input type="checkbox"/>		
	Not-eligible:		

<i>group)</i>	CACR vs CACR <input type="checkbox"/> CACR vs other <input type="checkbox"/>		
Types of outcome measures	Standardised functional outcome measures used at pre and post treatment stage	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
INCLUDE <input type="checkbox"/> EXCLUDE <input type="checkbox"/> NEAR MISS? <input type="checkbox"/>			
Reason for exclusion			
Notes:			

DO NOT PROCEED IF STUDY EXCLUDED FROM REVIEW

Characteristics of included studies

Methods

	Descriptions as stated in report/paper
Research question (e.g. efficacy, equivalence, pragmatic)	
Design (note any issues with equivalence of arms)	Single centre <input type="checkbox"/> Multi-centre: National <input type="checkbox"/> International <input type="checkbox"/> No. centres: ____ NR <input type="checkbox"/>
Groups (treatment, control etc.)	
Flow diagram?	
Method of randomisation	
Method of concealment of randomisation	NR <input type="checkbox"/> Adequate <input type="checkbox"/> (Please specify): Done + unclear <input type="checkbox"/> ; Not done <input type="checkbox"/> ; Inadequate <input type="checkbox"/>
Blinding (Single=patient only; double= +clinician; triple= +outcome assessor)	Single <input type="checkbox"/> Double <input type="checkbox"/> Triple <input type="checkbox"/> Not possible <input type="checkbox"/> No blinding <input type="checkbox"/> NR <input type="checkbox"/>

Participants

	Description <i>Include comparative information for each intervention or comparison group if available</i>
Population description <i>(from which study participants are drawn)</i>	
Setting <i>(including location and social context)</i>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Inpatient Outpatient Unclear NR
Inclusion criteria	
Exclusion criteria	
Total no. randomised <i>(or total pop. at start of study for NRCTs)</i>	
Baseline imbalances	
Number of withdrawals and exclusions <i>(if not provided below by outcome)</i>	
Age	
Sex	
Race/Ethnicity	
Socio-economic status	
Education level	

Intervention groups

Copy and paste table for each intervention and comparison group

Treatment Group

	Description as stated in report/paper
Group <i>(from paper)</i>	
No. randomised to group	
Age	
Sex (%)	Male: Female:
Race/Ethnicity (%)	
Socio-economic status (%)	
Education	
Description of intervention <i>(include sufficient detail for replication, e.g. content, dose, components)</i>	
Duration of treatment period	
Timing <i>(e.g. frequency, duration of each episode)</i>	
Delivery <i>(e.g. computer only? Therapist involved? To what extent – strategies? Encouragement?)</i>	

Control group

	Description as stated in report/paper
Group <i>(from paper)</i>	
No. randomised to group	
Age	
Sex (%)	Male: Female:
Race/Ethnicity (%)	
Socio-economic status (%)	
Education	
Description of intervention <i>(include sufficient detail for replication, e.g. content, dose, components)</i>	
Duration of treatment period	
Timing <i>(e.g. frequency, duration of each episode)</i>	
Delivery <i>(e.g. computer only? Therapist involved? To what extent – strategies? Encouragement?)</i>	

Other group

	Description as stated in report/paper
--	---------------------------------------

Group <i>(from paper)</i>	
No. randomised to group	
Age	
Sex (%)	Male: Female:
Race/Ethnicity (%)	
Socio-economic status (%)	
Education	
Description of intervention <i>(include sufficient detail for replication, e.g. content, dose, components)</i>	
Duration of treatment period	
Timing <i>(e.g. frequency, duration of each episode)</i>	
Delivery <i>(e.g. computer only? Therapist involved? To what extent – strategies? Encouragement?)</i>	

Outcomes

Copy and paste table for each outcome – i.e. each assessment of neuro functioning, functional outcomes, symptoms and any others assessed.

Outcome 1

	Description as stated in report/paper			
Outcome name (<i>as used in paper</i>)				
Assessment tool (<i>Name</i>)				
No. of patients evaluated for this outcome	All randomised	<input type="checkbox"/>		
	Unclear	<input type="checkbox"/>		
	Fewer	<input type="checkbox"/>	____%	
Domain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Neuro	Functional	Symptoms	Other
Construct	<i>Describe:</i>			
Is outcome/tool validated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Yes	No	Unclear	
Is outcome/tool validated for this population?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Yes	No	Unclear	
Time points measured/reported(<i>specify whether from start or end of intervention</i>)				

Outcome 2

	Description as stated in report/paper
--	---------------------------------------

Outcome name (<i>as used in paper</i>)				
Assessment tool (<i>Name</i>)				
No. of patients evaluated for this outcome	All randomised	<input type="checkbox"/>		
	Unclear	<input type="checkbox"/>		
	Fewer	<input type="checkbox"/>	____%	
Domain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Neuro	Functional	Symptoms	Other
Construct	<i>Describe:</i>			
Is outcome/tool validated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Yes	No	Unclear	
Is outcome/tool validated for this population?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Yes	No	Unclear	
Time points measured/reported(<i>specify whether from start or end of intervention</i>)				

Outcome 3

	Description as stated in report/paper	
Outcome name (<i>as used in paper</i>)		
Assessment tool (<i>Name</i>)		
No. of patients evaluated for this outcome	All randomised	<input type="checkbox"/>
	Unclear	<input type="checkbox"/>
	Fewer	<input type="checkbox"/> ____%

Domain	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
	Neuro Functional Symptoms Other
Construct	<i>Describe:</i>
Is outcome/tool validated?	<div> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> </div> <div> Yes No Unclear </div>
Is outcome/tool validated for this population?	<div> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> </div> <div> Yes No Unclear </div>
Time points measured/reported(<i>specify whether from start or end of intervention</i>)	

Data and Analysis

Copy and paste the appropriate table for **each outcome**, including additional tables for **each time point** and subgroup as required.

Outcome 1

	Description as stated in report/paper					
Outcome						
Time point (specify from start or end of intervention)	Pre-treatment					
Results	Intervention			Comparison		
	Mean	SD (or other variance, specify)	No. participants	Mean	SD (or other variance, specify)	No. participants
Any other results reported (e.g. mean difference, CI, P value)						
No. participants moved from other group						
Reasons moved						
Time point (specify from start or end of intervention)	Post-treatment					

Post-intervention or change from baseline?		Intervention Statistically significant change Yes <input type="checkbox"/> No <input type="checkbox"/> Enter p-value:		Comparison Statistically significant change Yes <input type="checkbox"/> No <input type="checkbox"/> Enter p-value:		
		If not sig. was it due to: <input type="checkbox"/> Evidence of absence of treatment effect (<i>i.e. clearly defined based on primary outcomes in the trial</i>) <input type="checkbox"/> No evidence for absence of treatment effect (<i>i.e. inconclusive, or low powered study</i>)(<i>i.e. not clearly defined or based on primary outcomes from the study</i>) <input type="checkbox"/> Unclear		If not sig. was it due to: <input type="checkbox"/> Evidence of absence of treatment effect (<i>i.e. clearly defined based on primary outcomes in the trial</i>) <input type="checkbox"/> No evidence for absence of treatment effect (<i>i.e. inconclusive, or low powered study</i>)(<i>i.e. not clearly defined or based on primary outcomes from the study</i>) <input type="checkbox"/> Unclear		
Results	Intervention			Comparison		
	Mean	SD (<i>or other variance, specify</i>)	No. participants	Mean	SD (<i>or other variance, specify</i>)	No. participants
Any other results reported (<i>e.g. mean difference, CI, P value</i>)						
No. missing participants						
Reasons missing						
No. participants moved from other group						
Reasons moved						
Time point (<i>specify from start or end of intervention</i>)		Follow-up				

Post-intervention or change from baseline?	Intervention Statistically significant change Yes <input type="checkbox"/> No <input type="checkbox"/> Enter p-value:			Comparison Statistically significant change Yes <input type="checkbox"/> No <input type="checkbox"/> Enter p-value:		
	If not sig. was it due to: <input type="checkbox"/> Evidence of absence of treatment effect (<i>i.e. clearly defined based on primary outcomes in the trial</i>) <input type="checkbox"/> No evidence for absence of treatment effect (<i>i.e. inconclusive, or low powered study</i>)(<i>i.e. not clearly defined or based on primary outcomes from the study</i>) <input type="checkbox"/> Unclear			If not sig. was it due to: <input type="checkbox"/> Evidence of absence of treatment effect (<i>i.e. clearly defined based on primary outcomes in the trial</i>) <input type="checkbox"/> No evidence for absence of treatment effect (<i>i.e. inconclusive, or low powered study</i>)(<i>i.e. not clearly defined or based on primary outcomes from the study</i>) <input type="checkbox"/> Unclear		
Results	Intervention			Comparison		
	Mean	SD (<i>or other variance, specify</i>)	No. participants	Mean	SD (<i>or other variance, specify</i>)	No. participants
Any other results reported (<i>e.g. mean difference, CI, P value</i>)						
No. missing participants						
Reasons missing						
No. participants moved from other group						
Reasons moved						

Outcome 2

	Description as stated in report/paper					
Outcome						
Time point <i>(specify from start or end of intervention)</i>	Pre-treatment					
Results	Intervention			Comparison		
	Mean	SD <i>(or other variance, specify)</i>	No. participants	Mean	SD <i>(or other variance, specify)</i>	No. participants
Any other results reported <i>(e.g. mean difference, CI, P value)</i>						
No. participants moved from other group						
Reasons moved						
Time point <i>(specify from start or end of intervention)</i>	Post-treatment					

Post-intervention or change from baseline?		Intervention Statistically significant change Yes <input type="checkbox"/> No <input type="checkbox"/> Enter p-value:		Comparison Statistically significant change Yes <input type="checkbox"/> No <input type="checkbox"/> Enter p-value:		
		If not sig. was it due to: <input type="checkbox"/> Evidence of absence of treatment effect (<i>i.e. clearly defined based on primary outcomes in the trial</i>) <input type="checkbox"/> No evidence for absence of treatment effect (<i>i.e. inconclusive, or low powered study</i>)(<i>i.e. not clearly defined or based on primary outcomes from the study</i>) <input type="checkbox"/> Unclear		If not sig. was it due to: <input type="checkbox"/> Evidence of absence of treatment effect (<i>i.e. clearly defined based on primary outcomes in the trial</i>) <input type="checkbox"/> No evidence for absence of treatment effect (<i>i.e. inconclusive, or low powered study</i>)(<i>i.e. not clearly defined or based on primary outcomes from the study</i>) <input type="checkbox"/> Unclear		
Results	Intervention			Comparison		
	Mean	SD (<i>or other variance, specify</i>)	No. participants	Mean	SD (<i>or other variance, specify</i>)	No. participants
Any other results reported (<i>e.g. mean difference, CI, P value</i>)						
No. missing participants						
Reasons missing						
No. participants moved from other group						
Reasons moved						
Time point (<i>specify from start or end of intervention</i>)		Follow-up				

Post-intervention or change from baseline?	Intervention Statistically significant change Yes <input type="checkbox"/> No <input type="checkbox"/> Enter p-value:			Comparison Statistically significant change Yes <input type="checkbox"/> No <input type="checkbox"/> Enter p-value:		
	If not sig. was it due to: <input type="checkbox"/> Evidence of absence of treatment effect (<i>i.e. clearly defined based on primary outcomes in the trial</i>) <input type="checkbox"/> No evidence for absence of treatment effect (<i>i.e. inconclusive, or low powered study</i>)(<i>i.e. not clearly defined or based on primary outcomes from the study</i>) <input type="checkbox"/> Unclear			If not sig. was it due to: <input type="checkbox"/> Evidence of absence of treatment effect (<i>i.e. clearly defined based on primary outcomes in the trial</i>) <input type="checkbox"/> No evidence for absence of treatment effect (<i>i.e. inconclusive, or low powered study</i>)(<i>i.e. not clearly defined or based on primary outcomes from the study</i>) <input type="checkbox"/> Unclear		
Results	Intervention			Comparison		
	Mean	SD (<i>or other variance, specify</i>)	No. participants	Mean	SD (<i>or other variance, specify</i>)	No. participants
Any other results reported (<i>e.g. mean difference, CI, P value</i>)						
No. missing participants						
Reasons missing						
No. participants moved from other group						
Reasons moved						

Outcome 3

	Description as stated in report/paper					
Outcome						
Time point <i>(specify from start or end of intervention)</i>	Pre-treatment					
Results	Intervention			Comparison		
	Mean	SD <i>(or other variance, specify)</i>	No. participants	Mean	SD <i>(or other variance, specify)</i>	No. participants
Any other results reported <i>(e.g. mean difference, CI, P value)</i>						
No. participants moved from other group						
Reasons moved						
Time point <i>(specify from start or end of intervention)</i>	Post-treatment					

Post-intervention or change from baseline?		Intervention Statistically significant change Yes <input type="checkbox"/> No <input type="checkbox"/> Enter p-value:		Comparison Statistically significant change Yes <input type="checkbox"/> No <input type="checkbox"/> Enter p-value:		
		If not sig. was it due to: <input type="checkbox"/> Evidence of absence of treatment effect (<i>i.e. clearly defined based on primary outcomes in the trial</i>) <input type="checkbox"/> No evidence for absence of treatment effect (<i>i.e. inconclusive, or low powered study</i>)(<i>i.e. not clearly defined or based on primary outcomes from the study</i>) <input type="checkbox"/> Unclear		If not sig. was it due to: <input type="checkbox"/> Evidence of absence of treatment effect (<i>i.e. clearly defined based on primary outcomes in the trial</i>) <input type="checkbox"/> No evidence for absence of treatment effect (<i>i.e. inconclusive, or low powered study</i>)(<i>i.e. not clearly defined or based on primary outcomes from the study</i>) <input type="checkbox"/> Unclear		
Results	Intervention			Comparison		
	Mean	SD (<i>or other variance, specify</i>)	No. participants	Mean	SD (<i>or other variance, specify</i>)	No. participants
Any other results reported (<i>e.g. mean difference, CI, P value</i>)						
No. missing participants						
Reasons missing						
No. participants moved from other group						
Reasons moved						
Time point (<i>specify from start or end of intervention</i>)		Follow-up				

Post-intervention or change from baseline?	Intervention Statistically significant change Yes <input type="checkbox"/> No <input type="checkbox"/> Enter p-value:			Comparison Statistically significant change Yes <input type="checkbox"/> No <input type="checkbox"/> Enter p-value:		
	If not sig. was it due to: <input type="checkbox"/> Evidence of absence of treatment effect (<i>i.e. clearly defined based on primary outcomes in the trial</i>) <input type="checkbox"/> No evidence for absence of treatment effect (<i>i.e. inconclusive, or low powered study</i>)(<i>i.e. not clearly defined or based on primary outcomes from the study</i>) <input type="checkbox"/> Unclear			If not sig. was it due to: <input type="checkbox"/> Evidence of absence of treatment effect (<i>i.e. clearly defined based on primary outcomes in the trial</i>) <input type="checkbox"/> No evidence for absence of treatment effect (<i>i.e. inconclusive, or low powered study</i>)(<i>i.e. not clearly defined or based on primary outcomes from the study</i>) <input type="checkbox"/> Unclear		
Results	Intervention			Comparison		
	Mean	SD (<i>or other variance, specify</i>)	No. participants	Mean	SD (<i>or other variance, specify</i>)	No. participants
Any other results reported (<i>e.g. mean difference, CI, P value</i>)						
No. missing participants						
Reasons missing						
No. participants moved from other group						
Reasons moved						

Appendix 1.3 – Quality Assessment Tool

Quality Assessment Tool		
AUTHOR: Martin Gallagher		
SUPERVISORS: Dr Suzanne O'Rourke, Dr Alana Davis, Prof Matthias Schwannauer		
DATE:		
ID:		
	Quality Criteria	Score
1. Sample		
1.1	Attrition rates are clearly stated and are similar for both treatment and control groups	
1.2	The treatment and control groups are similar at the start of the trial	
Total:		/4
2. Study design		
2.1	The study addresses an appropriate and clearly focused question	
2.2	The assignment of participants to groups is randomised	
2.3	An adequate concealment method is used	
2.4	Participants and investigators are kept 'blind' about treatment allocation	
2.5	The only difference between groups is the treatment under consideration	
2.6	Participants are followed-up sufficiently	
2.7	The control condition involves a qualitatively similar task to the experimental condition	
Total:		/14
3. Outcomes		
3.1	All relevant outcomes are measured in a standard, valid and reliable way	
Total:		/2
4. Results and statistical analysis		
4.1	All the participants are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	
4.2	Where the study is carried out at more than one site, results are comparable for all sites	
Total:		/4
OVERALL TOTAL:		/24

1. Sample			
1.1	Attrition rates are clearly stated and are similar for both treatment and control groups		
	Well covered (2)	Attrition rates (between pre and post treatment stages) are clearly stated for both groups. Attrition rates should be within 10% of each other for treatment and control groups. Attrition rates should be less than 20% of the total.	
	Adequately addressed (1)	Attrition rates are clearly stated for both groups. Attrition rates should be within 20% of each other for treatment and control groups. Attrition rates should be less than 30% of the total.	
	Poorly addressed (0)	Attrition rates are significantly different between groups or account for a significant proportion of the total.	
	Not addressed (0)		
	Not reported (0)		
	Not applicable (0)		
1.2	The treatment and control groups are similar at the start of the trial		
	Well covered (2)	Full details of baseline characteristics are given (e.g. gender, age, diagnosis, years of education, cognitive functioning etc.). Groups are sufficiently alike at baseline <u>or</u> any differences are controlled for during the analysis.	
	Adequately addressed (1)	Reasonable details of baseline characteristics are given. Groups are somewhat alike.	
	Poorly addressed (0)	Limited details of baseline characteristics are given or baseline differences are not controlled for during the analysis.	
	Not addressed (0)		
	Not reported (0)		
	Not applicable (0)		
Total section 1:			/4
2. Study design			
2.1	The study addresses an appropriate and clearly focused question		
	Well covered (2)	An appropriate and clearly focused research question is described, with clearly stated hypotheses.	
	Adequately addressed (1)	A research question is described, however it may be lacking in clarity or focus and hypotheses are not clearly stated.	
	Poorly addressed (0)	The research question is unclear.	
	Not addressed (0)		
	Not reported (0)		
	Not applicable (0)		
2.2	The assignment of participants to groups is randomised		
	Well covered (2)	The randomisation process is clearly described and uses an appropriate method. (e.g.	
	Adequately addressed (1)	The paper states that a randomisation process was used but the process itself is not clearly described.	
	Poorly addressed (0)	The paper states that a randomisation process is used but the method is not appropriate.	
	Not addressed (0)		

	Not reported (0)		
	Not applicable (0)		
2.3	An adequate concealment method is used		
	Well covered (2)	An appropriate method is used to ensure that researchers are unaware of the group that participants are being allocated to at the time of entry to the study. The method is clearly described.	
	Adequately addressed (1)	Concealment appears to have been carried out, however a clear description is not given.	
	Poorly addressed (0)	The method of concealment is likely to be ineffective at ensuring researchers are unaware of the group that participants are being allocated to at the time of entry to the study.	
	Not addressed (0)		
	Not reported (0)		
	Not applicable (0)		
2.4	Participants and investigators are kept 'blind' about treatment allocation		
	Well covered (2)	Both participants and those scoring/interpreting the results are blind to treatment condition.	
	Adequately addressed (1)	Those scoring/interpreting the results are blind to the treatment condition but the participants are not.	
	Poorly addressed (0)	Those scoring/interpreting the results are aware of the treatment condition.	
	Not addressed (0)		
	Not reported (0)		
	Not applicable (0)		
2.5	The only difference between groups is the treatment under consideration		
	Well covered (2)	It is clear that groups were treated equally and that no additional treatment was given that could be a potential confounding factor.	
	Adequately addressed (1)	Reasonably clear that no additional treatment was given that could be a potential confounding factor.	
	Poorly addressed (0)	It is unclear whether any additional treatment was given that could be a potential confounding factor.	
	Not addressed (0)		
	Not reported (0)		
	Not applicable (0)		
2.6	Participants are followed-up sufficiently		
	Well covered (2)	Follow-up occurs 6 months or more after post-treatment assessments	
	Adequately addressed (1)	Follow-up occurs 3 to 5 months after post-treatment assessments	
	Poorly addressed (0)	Follow up occurs less than 3 months after post-treatment assessments	
	Not addressed (0)		
	Not reported (0)		

	Not applicable (0)		
2.7	The control condition involves a qualitatively similar task to the experimental condition		
	Well covered (2)	The control condition involves completing a computer task	
	Adequately addressed (1)	An active control group is used, but does not involve a computer task	
	Poorly addressed (0)	The control condition contains no active element (i.e. involves TAU)	
	Not addressed (0)		
	Not reported (0)		
	Not applicable (0)		
Total section 2:			/14
3. Outcomes			
3.1	All relevant outcomes are measured in a standard, valid and reliable way		
	Well covered (2)	Standardised measures are used with well reported psychometric properties in this population.	
	Adequately addressed (1)	Standardised measures are used with adequate psychometric properties, however there is little evidence of reliability/validity in this population.	
	Poorly addressed (0)	Non-standardised measures are used	
	Not addressed (0)		
	Not reported (0)		
	Not applicable (0)		
Total section 3:			/2
4. Results and Statistical Analysis			
4.1	All the participants are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)		
	Well covered (2)	An intention to treat analysis is carried out and described in detail, with all participants analysed in the groups to which they were randomly allocated	
	Adequately addressed (1)	An intention to treat analysis is carried out, however few details are given	
	Poorly addressed (0)	It is unclear if an intention to treat analysis is carried out or this was not carried out appropriately.	
	Not addressed (0)		
	Not reported (0)		
	Not applicable (0)		
4.2	Where the study is carried out at more than one site, results are comparable for all sites		
	Well covered (2)	Detailed results from each site are given. These are compared and any differences are controlled the analysis	
	Adequately addressed (1)	Limited details of the results from each site are given. These are compared and any differences are controlled in the analysis	
	Poorly addressed (0)	No details of the results from each site are given or any differences are not controlled in the analysis.	
	Not addressed (0)		
	Not reported (0)		

	Not applicable (0)		
Total section 5:			/4

Appendix 1.4 – Papers excluded following the full-text review

Reference	Reason for exclusion
An, S., Oh, B., Hyun, M., & Yoo, K. (1997). The Effect of Attention Training Using Computer-Aided Cognitive Rehabilitation Program (REHACOM) in Chronic Schizophrenics. <i>Journal of the Korean Neuropsychiatric Association</i> , 36(1), 72–79.	Non-English language
Bark, N., Revheim, N., Huq, F., Khaldarov, V., Ganz, Z. W., & Medalia, A. (2003). The impact of cognitive remediation on psychiatric symptoms of schizophrenia. <i>Schizophrenia Research</i> , 63(3), 229–235.	No functional outcome measure
Bell, M., Bryson, G., Greig, T., Corcoran, C., & Wexler, B. (2001). Neurocognitive enhancement therapy with work therapy: effects on neuropsychological test performance. <i>Archives of General Psychiatry</i> , 58, 763–768.	No functional outcome measure (uses employment data rather than a functional outcome scale)
Bell, M., Bryson, G., & Wexler, B. E. (2003). Cognitive remediation of working memory deficits: durability of training effects in severely impaired and less severely impaired schizophrenia. <i>Acta Psychiatrica Scandinavica</i> , 108(2), 101–109.	No functional outcome measure
Bell, M. D., Bryson, G. J., Greig, T. C., Fiszdon, J. M., & Wexler, B. E. (2005). Neurocognitive enhancement therapy with work therapy: Productivity outcomes at 6- and 12-month follow-ups. <i>The Journal of Rehabilitation Research and Development</i> , 42(6), 829.	No functional outcome measure (uses employment data rather than a functional outcome scale)
Bell, M. D., Fiszdon, J. M., & Bryson, G. (2009). Attention training in schizophrenia: Differing responses to similar tasks. <i>Journal of Psychiatric Research</i> , 43(4).	No control group
Bell, M. D., Zito, W., Greig, T., & Wexler, B. E. (2008). Neurocognitive enhancement therapy with vocational services: Work outcomes at two-year follow-up. <i>Schizophrenia Research</i> , 105(1-3), 18–29.	No functional outcome measure (uses employment data rather than a functional outcome scale)
Bell, M., Fiszdon, J., Greig, T., Wexler, B., & Bryson, G. (2007). Neurocognitive enhancement therapy with work therapy in schizophrenia: 6-month follow-up of neuropsychological performance. <i>The Journal of Rehabilitation Research and Development</i> , 44(5), 761.	No functional outcome measure
Bell, M., Zito, W., Greig, T., & Wexler, B. E. (2008). Neurocognitive Enhancement Therapy and Competitive Employment in Schizophrenia: Effects on Clients with Poor Community Functioning. <i>American Journal of Psychiatric Rehabilitation</i> , 11(2), 109–122.	No functional outcome measure (uses employment data rather than a functional outcome scale)
Bellucci, D. M., Glaberman, K., & Haslam, N. (2003). Computer-assisted cognitive rehabilitation reduces negative symptoms in the severely mentally ill. <i>Schizophrenia Research</i> , 59(2), 225–232.	No functional outcome measure
Benedict, R. H., & Harris, A. E. (1989). Remediation of	No functional outcome

attention deficits in chronic schizophrenic patients: a preliminary study. <i>British Journal of Clinical Psychology</i> , 28(2), 187–188.	measure
Benedict, R. H., Harris, A. E., Markow, T., McCormick, J. A., Nuechterlein, K. H., & Asarnow, R. F. (1994). Effects of attention training on information processing in schizophrenia. <i>Schizophrenia Bulletin</i> , 20(3), 537–546.	No functional outcome measure
Bor, J., Brunelin, J., d' Amato, T., Costes, N., Suaud-Chagny, M.-F., Saoud, M., & Poulet, E. (2011). How can cognitive remediation therapy modulate brain activations in schizophrenia? <i>Psychiatry Research: Neuroimaging</i> , 192(3), 160–166.	No functional outcome measure
Bosia, M., Bechi, M., Marino, E., Anselmetti, S., Poletti, S., Cocchi, F., Smeraldi, E., & Cavallaro, R. (2007). Influence of catechol-O-methyltransferase Val158Met polymorphism on neuropsychological and functional outcomes of classical rehabilitation and cognitive remediation in schizophrenia. <i>Neuroscience Letters</i> , 417(3), 271–274.	No valid control condition (Both treatment and control group involve treatment targeting neuropsychological functioning)
Bowie, C. R., Grossman, M., Gupta, M., Oyewumi, L. K., & Harvey, P. D. (2014). Cognitive remediation in schizophrenia: efficacy and effectiveness in patients with early versus long-term course of illness. <i>Early Intervention in Psychiatry</i> , 8(1), 32–38.	No valid control condition (Involves two treatment conditions that target neuropsychological functioning)
Brown, C., Harwood, K., Hays, C., & Heckman, J. (1993). Effectiveness of cognitive rehabilitation for improving attention in patients with schizophrenia. <i>Occupational Therapy Journal of Research</i> , 13(2), 71–86.	No valid control condition (Involves two treatment conditions that target neuropsychological functioning)
Burda, P. C., Starkey, T. W., Dominguez, F., & Vera, V. (1994). Computer-assisted cognitive rehabilitation of chronic psychiatric inpatients. <i>Computers in Human Behaviour</i> , 10(3), 359–368.	No functional outcome measure
Cassidy, J. J., Easton, M., Capelli, C., Singer, A., & Bilodeau, A. (1996). Cognitive remediation of persons with severe and persistent mental illness. <i>Psychiatric Quarterly</i> , 67(4), 313–321.	No control condition
Cella, M., Bishara, A. J., Medin, E., Swan, S., Reeder, C., & Wykes, T. (2013). Identifying Cognitive Remediation Change Through Computational Modelling--Effects on Reinforcement Learning in Schizophrenia.	Non-computerised CR. No randomisation to treatment conditions
Chan, C. L. ., Ngai, E. K. ., Leung, P. K. H., & Wong, S. (2009). Effect of the adapted virtual reality cognitive training program among Chinese older adults with chronic schizophrenia: a pilot study. <i>International Journal of Geriatric Psychiatry</i> .	No functional outcome measure
Eack, S. M., Hogarty, G. E., Cho, R. Y., Prasad, K. M.,	No functional outcome

Greenwald, D. P., Hogarty, S. S., & Keshavan, M. S. (2010). Neuroprotective effects of cognitive enhancement therapy against gray matter loss in early schizophrenia. <i>Arch Gen Psychiatry</i> , 67(7), 674–682.	measure
Eack, S. M., Mesholam-Gately, R. I., Greenwald, D. P., Hogarty, S. S., & Keshavan, M. S. (2013). Negative symptom improvement during cognitive rehabilitation: Results from a 2-year trial of Cognitive Enhancement Therapy. <i>Psychiatry Research</i> , 209(1), 21–26.	No functional outcome measure
Edwards, B. G. ., Barch, D. M., & Braver, T. S. (2010). Improving prefrontal cortex function in schizophrenia through focused training of cognitive control. <i>Frontiers in Human Neuroscience</i> .	No randomisation. Participants in control condition did not have schizophrenia or schizoaffective disorder
Farreny, A., Aguado, J., Ochoa, S., Haro, J. M., & Usall, J. (2013). The role of negative symptoms in the context of cognitive remediation for schizophrenia. <i>Schizophrenia Research</i> , 150(1), 58–63.	Non-computerised CR
Field, C. D., Galletly, C., Anderson, D., & Walker, P. (1997). Computer-aided cognitive rehabilitation: possible application to the attentional deficit of schizophrenia, a report of negative results. <i>Perceptual and Motor Skills</i> , 85(3), 995–1002.	No randomisation
Fiszdon, J. M., Whelahan, H., Bryson, G. J., Wexler, B. E., & Bell, M. D. (2005). Cognitive training of verbal memory using a dichotic listening paradigm: impact on symptoms and cognition. <i>Acta Psychiatrica Scandinavica</i> , 112(3), 187–193.	No functional outcome measure
Fiszdon, J.M., Choi, J., Bryson, G. J., & Bell, M. D. (2006). Impact of intellectual status on response to cognitive task training in patients with schizophrenia. <i>Schizophrenia Research</i> , 87(1-3), 261–269.	No functional outcome measure
Fiszdon, Joanna M, Bryson, G. J., Wexler, B. E., & Bell, M. D. (2004). Durability of cognitive remediation training in schizophrenia: performance on two memory tasks at 6-month and 12-month follow-up. <i>Psychiatry Research</i> , 125(1), 1–7.	No functional outcome measure
Fiszdon, Joanna M., Cardenas, A. S., Bryson, G. J., & Bell, M. D. (2005). Predictors of Remediation Success on a Trained Memory Task: <i>The Journal of Nervous and Mental Disease</i> , 193(9), 602–608.	No functional outcome measure
Franck, N., Duboc, C., Sundby, C., Amado, I., Wykes, T., Demily, C., ... Vianin, P. (2013). Specific vs general cognitive remediation for executive functioning in schizophrenia: A multicenter randomized trial. <i>Schizophrenia Research</i> , 147(1), 68–74.	Non-computerised CR
Gharaeipour, M., & Scott, B. (2012). Effects of cognitive	Non-computerised CR

remediation on neurocognitive functions and psychiatric symptoms in schizophrenia inpatients. <i>Schizophrenia Research</i> , 142(1-3), 165–170.	
Greenwood, K., Hung, C.-F., Tropeano, M., McGuffin, P., & Wykes, T. (2011). No association between the Catechol-O-Methyltransferase (COMT) val158met polymorphism and cognitive improvement following cognitive remediation therapy (CRT) in schizophrenia. <i>Neuroscience Letters</i> , 496(2), 65–69.	Non-computerised CR
Greig, T., Zito, W., Wexler, B., Fiszdon, J., & Bell, M. (2007). Improved cognitive function in schizophrenia after one year of cognitive training and vocational services. <i>Schizophrenia Research</i> , 96(1-3), 156–161.	No functional outcome measure
Haut, K. M., Lim, K. O., & MacDonald, A. (2010). Prefrontal cortical changes following cognitive training in patients with chronic schizophrenia: effects of practice, generalization, and specificity. <i>Neuropsychopharmacology</i> , 35(9), 1850–1859.	No functional outcome measure
Hermanutz, M., & Gestrich, J. (1991). Computer-assisted attention training in schizophrenics. <i>European Archives of Psychiatry and Clinical Neuroscience</i> , 240(4-5), 282–287.	No functional outcome measure
Hooker, C. I., Bruce, L., Fisher, M., Verosky, S. C., Miyakawa, A., D'Esposito, M., & Vinogradov, S. (2013). The influence of combined cognitive plus social-cognitive training on amygdala response during face emotion recognition in schizophrenia. <i>Psychiatry Research: Neuroimaging</i> , 213(2), 99–107.	No randomisation
Hooker, C. I., Bruce, L., Fisher, M., Verosky, S. C., Miyakawa, A., & Vinogradov, S. (2012). Neural activity during emotion recognition after combined cognitive plus social cognitive training in schizophrenia. <i>Schizophrenia Research</i> , 139(1-3), 53–59.	No randomisation
Horan, W. P., Kern, R. S., Tripp, C., Helleman, G., Wynn, J. K., Bell, M., ... Green, M. F. (2011). Efficacy and specificity of Social Cognitive Skills Training for outpatients with psychotic disorders. <i>Journal of Psychiatric Research</i> , 45(8), 1113–1122.	Includes participants with diagnoses other than schizophrenia or schizoaffective disorder
Ikezawa, S., Mogami, T., Hayami, Y., Sato, I., Kato, T., Kimura, I., ... Nakagome, K. (2012). The pilot study of a Neuropsychological Educational Approach to Cognitive Remediation for patients with schizophrenia in Japan. <i>Psychiatry Research</i> , 195(3), 107–110.	No functional outcome measure
Kidd, S. A., Kaur Bajwa, J., McKenzie, K. J., Ganguli, R., & Haji Khamneh, B. (2012). Cognitive Remediation for Individuals with Psychosis in a Supported Education Setting: A Pilot Study. <i>Rehabilitation Research and</i>	No control group

<i>Practice</i> , 2012, 1–5.	
Kontis, D., Huddy, V., Reeder, C., Landau, S., & Wykes, T. (2013). Effects of Age and Cognitive Reserve on Cognitive Remediation Therapy Outcome in Patients With Schizophrenia. <i>The American Journal of Geriatric Psychiatry</i> , 21(3), 218–230.	No valid control condition (Involves two treatment conditions that target neuropsychological functioning)
Kurtz, M. M., Seltzer, J. C., Fujimoto, M., Shagan, D. S., & Wexler, B. E. (2009). Predictors of change in life skills in schizophrenia after cognitive remediation. <i>Schizophrenia Research</i> , 107(2-3), 267–274.	No control group
Kurtz, M. M., Seltzer, J. C., Shagan, D. S., Thime, W. R., & Wexler, B. E. (2007). Computer-assisted cognitive remediation in schizophrenia: What is the active ingredient? <i>Schizophrenia Research</i> , 89(1-3), 251–260.	No functional outcome measure
Kurtz, M. M., Wexler, B. E., Fujimoto, M., Shagan, D. S., & Seltzer, J. C. (2008). Symptoms versus neurocognition as predictors of change in life skills in schizophrenia after outpatient rehabilitation. <i>Schizophrenia Research</i> , 102(1), 303–311.	No control group
Lewandowski, K. E., Eack, S. M., Hogarty, S. S., Greenwald, D. P., & Keshavan, M. S. (2011). Is cognitive enhancement therapy equally effective for patients with schizophrenia and schizoaffective disorder? <i>Schizophrenia Research</i> , 125(2-3), 291–294.	No randomisation
Lewis, L., Unkefer, E. P., O’Neal, S. K., Crith, C. J., & Fultz, J. (2003). Cognitive Rehabilitation with Patients Having Persistent, Severe Psychiatric Disabilities. <i>Psychiatric Rehabilitation Journal</i> , 26(4), 325–331.	Non-computerised CR
Lindenmayer, J.-P., McGurk, S. R., Khan, A., Kaushik, S., Thanju, A., Hoffman, L., ... Herrmann, E. (2013). Improving Social Cognition in Schizophrenia: A Pilot Intervention Combining Computerized Social Cognition Training With Cognitive Remediation. <i>Schizophrenia Bulletin</i> , 39(3), 507–517.	No valid control condition (Involves two treatment conditions that target neuropsychological functioning)
Lindenmayer, Jean-Pierre, McGurk, S. R., Mueser, K., Khan, A., Wance, D., Hoffman, L., ... Xie, H. (2008). A randomized controlled trial of cognitive remediation among inpatients with persistent mental illness. <i>Psychiatric Services</i> , 59(3), 241–247.	No functional outcome measure
López-Luengo, B., & Vázquez, C. (2003). Effects of Attention Process Training on cognitive functioning of schizophrenic patients. <i>Psychiatry Research</i> , 119(1-2), 41–53.	Non-computerised CR
Mak, M., Samochowiec, J., Tybura, P., Bienkowski, P., Karakiewicz, B., Zaremba-Pechmann, L., & Mroczek, B. (2013). The efficacy of cognitive rehabilitation with RehaCom programme in schizophrenia patients: The	No functional outcome measure

role of selected genetic polymorphisms in successful cognitive. <i>Annals of Agricultural and Environmental Medicine</i> , 20(1), 77–81.	
Man, D., Law, K., & Chung, R. (2012). Cognitive training for Hong Kong Chinese with schizophrenia in vocational rehabilitation. <i>Hong Kong Medical Journal</i> , 18(6), 18–22.	No valid functional outcome measure
McGurk, S., Mueser, K., Feldman, K., Wolfe, R., & Pascaris, A. (2007). Cognitive training for supported employment: 2-3 year outcomes of a randomized controlled trial. <i>American Journal of Psychiatry</i> , 164(3), 437–441.	Includes participants with diagnoses other than schizophrenia or schizoaffective disorder
McGurk, S. R., Mueser, K., & Pascaris, A (2005). Cognitive Training and Supported Employment for Persons With Severe Mental Illness: One-Year Results From a Randomized Controlled Trial. <i>Schizophrenia Bulletin</i> , 31(4), 898–909.	Includes participants with diagnoses other than schizophrenia or schizoaffective disorder
McGurk, S. R., & Mueser, K. T. (2008). Response to Cognitive Rehabilitation in Older Versus Younger Persons with Severe Mental Illness. <i>American Journal of Psychiatric Rehabilitation</i> , 11(1), 90–105.	Includes participants with diagnoses other than schizophrenia or schizoaffective disorder
McGurk, S. R., Mueser, K. T., DeRosa, T. J., & Wolfe, R. (2009). Work, Recovery, and Comorbidity in Schizophrenia: A Randomized Controlled Trial of Cognitive Remediation. <i>Schizophrenia Bulletin</i> , 35(2), 319–335.	Includes participants with diagnoses other than schizophrenia or schizoaffective disorder
McGurk, Susan R., Schiano, D., Mueser, K. T., & Wolfe, R. (2010). Implementation of the thinking skills for work program in a psychosocial clubhouse. <i>Psychiatric Rehabilitation Journal</i> , 33(3), 190–199.	No control group
Medalia, A., Aluma, M., Tryon, W., & Merriam, A. E. (1998). Effectiveness of attention training in schizophrenia. <i>Schizophrenia Bulletin</i> , 24(1), 147–152.	No functional outcome measure
Medalia, A., Revheim, N., & Casey, M. (2000). Remediation of memory disorders in schizophrenia. <i>Psychological Medicine</i> , 30(06), 1451–1459.	No functional outcome measure
Medalia, A., Revheim, N., & Casey, M. (2001). The remediation of problem-solving skills in schizophrenia. <i>Schizophrenia Bulletin</i> , 27(2), 259.	No functional outcome measure
Medalia, A., Revheim, N., & Casey, M. (2002). Remediation of problem-solving skills in schizophrenia: evidence of a persistent effect. <i>Schizophrenia Research</i> , 57(2), 165–171.	No functional outcome measure
Murthy, N. V., Mahncke, H., Wexler, B. E., Maruff, P., Inamdar, A., Zucchetto, M., ... Alexander, R. (2012). Computerized cognitive remediation training for schizophrenia: an open label, multi-site, multinational	No control group

methodology study. <i>Schizophrenia Research</i> , 139(1), 87–91.	
Olbrich, R., & Mussgay, L. (1990). Reduction of schizophrenic deficits by cognitive training: an evaluative study. <i>European Archives of Psychiatry and Neurological Sciences</i> , 239(6), 366–369.	Non-computerised CR
Panizzutti, R., Hamilton, S. P., & Vinogradov, S. (2013). Genetic correlate of cognitive training response in schizophrenia. <i>Neuropharmacology</i> , 64, 264–267.	No functional outcome measure
Penadés, R., Boget, T., Lomena, F., Mateos, J. ., Catalan, R., Gastó, C., & Salamero, M. (2002). Could the hypofrontality pattern in schizophrenia be modified through neuropsychological rehabilitation. <i>Acta Psychiatrica Scandinavica</i> , 105, 202–208.	No control group
Penadés, Rafael, Catalán, R., Salamero, M., Boget, T., Puig, O., Guarch, J., & Gastó, C. (2006). Cognitive Remediation Therapy for outpatients with chronic schizophrenia: A controlled and randomized study. <i>Schizophrenia Research</i> , 87(1-3), 323–331.	Non-computerised CR
Penadés, Rafael, Pujol, N., Catalán, R., Massana, G., Rametti, G., García-Rizo, C., ... Junqué, C. (2013). Brain Effects of Cognitive Remediation Therapy in Schizophrenia: A Structural and Functional Neuroimaging Study. <i>Biological Psychiatry</i> , 73(10), 1015–1023.	Non-computerised CR
Popov, T., Jordanov, T., Rockstroh, B., Elbert, T., Merzenich, M. M., & Miller, G. A. (2011). Specific Cognitive Training Normalizes Auditory Sensory Gating in Schizophrenia: A Randomized Trial. <i>Biological Psychiatry</i> , 69(5), 465–471.	No valid control condition (Involves two treatment conditions that target neuropsychological functioning)
Rass, O., Forsyth, J. K., Bolbecker, A. R., Hetrick, W. P., Breier, A., Lysaker, P. H., & O'Donnell, B. F. (2012). Computer-assisted cognitive remediation for schizophrenia: a randomized single-blind pilot study. <i>Schizophrenia Research</i> , 139(1), 92–98.	No functional outcome measure
Rauchensteiner, S., Kawohl, W., Ozgurdal, S., Littmann, E., Gudlowski, Y., Witthaus, H., ... Juckel, G. (2011). Test-performance after cognitive training in persons at risk mental state of schizophrenia and patients with schizophrenia. <i>Psychiatry Research</i> , 185(3), 334–339.	No valid control condition (Involves two treatment conditions that target neuropsychological functioning). No randomisation
Reeder, C. (2006). Cognitive Predictors of Social Functioning Improvements Following Cognitive Remediation for Schizophrenia. <i>Schizophrenia Bulletin</i> , 32(Supplement 1), S123–S131.	Non-computerised CR
Reeder, Clare, Newton, E., Frangou, S., & Wykes, T. (2004). Which executive skills should we target to	Non-computerised CR

affect social functioning and symptom change? A study of a cognitive remediation therapy program. <i>Schizophrenia Bulletin</i> , 30(1), 87.	
Rodewald, K., Rentrop, M., Holt, D. V., Roesch-Ely, D., Backenstraß, M., Funke, J., ... Kaiser, S. (2011). Planning and problem-solving training for patients with schizophrenia: a randomized controlled trial. <i>BMC Psychiatry</i> , 11(1), 73.	No valid control condition (Involves two treatment conditions that target neuropsychological functioning).
Rosenbaum, G., Taylor, M., & Minasian, G. (1997). Normalizing the crossover effect - enhancement of cognitive attentional processing in schizophrenia. <i>Psychiatry Research</i> , 72(3), 167–176.	No randomisation (Control condition involves subjects without a diagnosis of schizophrenia or schizoaffective disorder)
Royer, A., Grosselin, A., Bellot, C., Pellet, J., Billard, S., Lang, F., ... Massoubre, C. (2012). Is there any impact of cognitive remediation on an ecological test in schizophrenia? <i>Cognitive Neuropsychiatry</i> , 17(1), 19–35.	Involves non-computerised CR
Rudnick, A., & Gover, M. (2009). Combining supported education with supported employment. <i>Psychiatric Services</i> , 60(12), 1690.	No control condition
Sacks, S., Fisher, M., Garrett, C., Alexander, P., Holland, C., Rose, D., ... Vinogradov, S. (2013). Combining computerized social cognitive training with neuroplasticity-based auditory training in schizophrenia. <i>Clinical Schizophrenia & Related Psychoses</i> , 7(2), 78–86A.	No control condition
Sanchez, P., Pena, J., Bengoetxea, E., Ojeda, N., Elizagarate, E., Ezcurra, J., & Gutierrez, M. (2014). Improvements in Negative Symptoms and Functional Outcome After a New Generation Cognitive Remediation Program: A Randomized Controlled Trial. <i>Schizophrenia Bulletin</i> , 40(3), 707–715.	Non-computerised CR
Sartory, G., Zorn, C., Groetzinger, G., & Windgassen, K. (2005). Computerized cognitive remediation improves verbal learning and processing speed in schizophrenia. <i>Schizophrenia Research</i> , 75(2-3), 219–223.	No functional outcome measure
Scheu, F., Aghotor, J., Pfueller, U., Moritz, S., Bohn, F., Weisbrod, M., & Roesch-Ely, D. (2013). Predictors of performance improvements within a cognitive remediation program for schizophrenia. <i>Psychiatry Research</i> , 209(3), 375–380.	No control condition
Subramaniam, K., Luks, T. L., Fisher, M., Simpson, G. V., Nagarajan, S., & Vinogradov, S. (2012). Computerized Cognitive Training Restores Neural Activity within the Reality Monitoring Network in Schizophrenia. <i>Neuron</i> , 73(4), 842–853.	No functional outcome measure

Surti, T. S., Corbera, S., Bell, M. D., & Wexler, B. E. (2011). Successful computer-based visual training specifically predicts visual memory enhancement over verbal memory improvement in schizophrenia. <i>Schizophrenia Research</i> , 132(2-3), 131–134.	No control condition
Surti, T. S., & Wexler, B. E. (2012). A pilot and feasibility study of computer-based training for visual processing deficits in schizophrenia. <i>Schizophrenia Research</i> , 142(1-3), 248–249.	No control condition
Trapp, W., Hasmann, A., Gallhofer, B., Schwerdtner, J., Guenther, W., & Dobmeier, M. (2008). Cognitive improvement of schizophrenia patients: Enhancing cognition while enjoying computer-aided cognitive training. <i>Clinical Schizophrenia & Related Psychoses</i> , 1(4), 307–316.	No randomisation
Trapp, W., Landgrebe, M., Hoesl, K., Lautenbacher, S., Gallhofer, B., Günther, W., & Hajak, G. (2013). Cognitive remediation improves cognition and good cognitive performance increases time to relapse—results of a 5 year catamnestic study in schizophrenia patients. <i>BMC Psychiatry</i> , 13(1), 184.	No randomisation
Tsang, M. M. Y., & Man, D. W. K. (2013). A virtual reality-based vocational training system (VRVTS) for people with schizophrenia in vocational rehabilitation. <i>Schizophrenia Research</i> , 144(1-3), 51–62.	No functional outcome measure
Twamley, E. W., Burton, C. Z., & Vella, L. (2011). Compensatory cognitive training for psychosis: who benefits? who stays in treatment? <i>Schizophrenia Bulletin</i> , 37(suppl 2), S55–S62.	Non-computerised CR
Van der Gaag, M., Kern, R. S., van den Bosch, R. J., & Liberman, R. P. (2002). A controlled trial of cognitive remediation in schizophrenia. <i>Schizophrenia Bulletin</i> , 28(1), 167–176.	Non-computerised CR
Vauth, R., Corrigan, P. W., Clauss, M., Margarete, D., Dreher-Rudolph, M., Stieglitz, R.-D., & Vater, R. (2005). Cognitive Strategies Versus Self-Management Skills as Adjunct to Vocational Rehabilitation. <i>Schizophrenia Bulletin</i> , 31(1), 55–66.	No functional outcome measure (uses employment data rather than a functional outcome scale)
Ventura, J., Wilson, S. A., Wood, R. C., & Helleman, G. (2013). Cognitive training at home in schizophrenia is feasible. <i>Schizophrenia Research</i> , 143, 397–398.	No control condition
Vianin, P., Urben, S., Magistretti, P., Marquet, P., Fornari, E., & Jaugey, L. (2014). Increased activation in Broca's area after cognitive remediation in schizophrenia. <i>Psychiatry Research: Neuroimaging</i> , 221(3), 204–209.	Includes non-computerised CR
Vinogradov, S. (2010). Cognitive training in	No functional outcome

schizophrenia: a neuroscience-based approach. <i>Dialogues in Clinical Neuroscience</i> . Retrieved from http://escholarship.org/uc/item/8tn9z1c0.pdf	measure
Vinogradov, S., Fisher, M., Holland, C., Shelly, W., Wolkowitz, O., & Mellon, S. H. (2009). Is Serum Brain-Derived Neurotrophic Factor a Biomarker for Cognitive Enhancement in Schizophrenia? <i>Biological Psychiatry</i> , 66(6), 549–553.	No functional outcome measure
Vinogradov, S., Fisher, M., Warm, H., Holland, C., Kirshner, M., & Pollock, B. (2009). The cognitive cost of anticholinergic burden: decreased response to cognitive training in schizophrenia. <i>American Journal of Psychiatry</i> , 166(9), 1055–1062.	No functional outcome measure
Vita, A., De Peri, L., Barlati, S., Cacciani, P., Cisma, M., Deste, G., ... Sacchetti, E. (2011). Psychopathologic, neuropsychological and functional outcome measures during cognitive rehabilitation in schizophrenia: A prospective controlled study in a real-world setting. <i>European Psychiatry</i> , 26(5), 276–283.	Non-computerised CR
Wexler, B. E., Anderson, M., Fulbright, R. K., & Gore, J. C. (2000). Preliminary evidence of improved verbal working memory performance and normalization of task-related frontal lobe activation in schizophrenia following cognitive exercises. <i>American Journal of Psychiatry</i> , 157(10), 1694–1697.	No control group

Appendix 1.5 – Description of Outcome Measures Used Across Studies

Outcome name	Abbreviation	Assessment Modality	Description
1. Adaptive composite	AC	Performance based	Composite of UPSA (see below), Maryland Assessment of Social Competence, and Advanced Finances Test. Aims to measure “functional competence”, defined as “skills that are important for independent living” (Bowie et al, 2012)
2. The Interview for the Assessment of Disability	AD	Interview based	Focuses on personal and social functioning over the past month. Covers work and social functioning among other areas.
3. Social Autonomy Scale	EAS	Clinician rated	Assesses skills in the following areas: personal care, management of daily life, resource management, external relations, emotional and social relationships
4. Global Assessment of Functioning	GAF	Clinician rated	Rates social, occupational and psychological functioning on a single item scale
5. Health of the Nation Outcome Scale	HoNOS	Clinician rated	Assesses individuals with severe mental illness in 12 scales covering the following domains: psychiatric symptoms, physical health, functioning, relationships, and housing,
6. Life Skills Profile	LSP	Clinician rated	Covers the following domains: self-care; nonturbulence; social contact; communication; and responsibility.
7. Medication Management Ability Assessment	MMAA	Performance based	Involves role-playing tasks involved in managing medication (e.g. taking medication at the appropriate time)
8. Personal and Social Performance Scale	PSP	Interview based	Measures social functioning across four domains: socially useful activities, personal and social

			relationships, self-care, and disturbing and aggressive behaviour.
9. Quality of life scale	QLS	Interview based	Assesses individuals' functioning across four functional domains: interpersonal relationships; symptoms; work performance; and other community activities.
10. Social Adjustment	SA	Interview based/clinician rated	Composite measure of "functional outcomes in the domains of social and vocational functioning, and adjustment in major life roles" (Eack et al, 2009)
11. Specific Levels of Functioning Scale	SLOF	Interview based*	Measures functioning across the following domains: self-maintenance; social functioning; and community living skills.
12. Social and Occupational Functioning Scale	SOFAS	Clinician rated	A single-item measure of social functioning
13. Schizophrenia Quality of Life	SQoL	Self-report	Assesses the following areas: psychosocial functioning; motivation and energy; and symptoms/side-effects.
14. Social Skills Performance Assessment	SSA	Performance based	Involves role-playing tasks relating to day-to-day social interactions with the aim of evaluating social competence (e.g. meeting a new neighbour).
15. University of California San Diego Performance-Based Skills Assessment Battery	UPSA	Performance based	Assesses individuals' ability to perform the following community functioning skills: managing money; communication; planning recreational activities; using transport; and completing household tasks.
16. Work-Behaviour Inventory	WBI	Interview based/ Performance based	Assesses work performance across the following categories: social skills; cooperativeness; work habits; work quality; and personal presentation. Assessments are made on the basis of observations and interview with the individuals' supervisor.

17. World Health Organization Quality of Life-BREF	WHOQOL- Bref	Self-report	Assesses the following domains: physical health; psychological health; social relationships; and environment.
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Chapter 2: Journal Article

The following journal article reports on the findings of a study investigating the implementation of computer assisted cognitive remediation in a high secure forensic psychiatric hospital. The article was written for submission to the International Journal of Forensic Mental Health. The journal's instructions for authors are provided in Appendix 2.1.

Abstract

Title: Implementing Computer Assisted Cognitive Remediation in a High Secure Forensic Psychiatric Setting

Shortened title: Computerised Cognitive Remediation in High Security

As both schizophrenia and offending behaviour are associated with cognitive deficits, computer assisted cognitive remediation (CACR) may benefit a forensic psychiatric population. This study explores the implementation of CACR in a high secure forensic psychiatric hospital. A high attrition rate was found, along with poor adherence to the treatment protocol. No clinical, risk or demographic factors distinguished treatment completers from those dropping out during treatment. An intention-to-treat analysis (n=20) found few improvements to performance on computer-based treatment activities or functional outcome measures. Motivational issues may have undermined outcomes, while functional deficits may be an inappropriate treatment target in this setting.

Word count: 7493

Introduction

Cognitive deficits have been described as a “core feature” of schizophrenia (Minzenberg & Carter, 2012) and are thought to be a significant contributor to the disabling difficulties with real-world functioning associated with the diagnosis (Green, Kern, Braff, & Mintz, 2000). This has led to the development of cognitive remediation therapy (CR), a group of interventions “targeting cognitive deficit (attention, memory, executive function, social cognition or meta cognition) using scientific principles of learning with the ultimate goal of improving functional outcomes” (McGurk et al., 2013).

Cognitive deficits, in areas such as executive functioning, have also been strongly associated with offending behaviour (e.g. Ogilvie, Stewart, Chan, & Shum, 2011). This has led to the suggestion that CR may also be beneficial to a forensic population, not only by contributing to risk management (O’Rourke, 2013) but also by enhancing outcomes of treatment programmes (Ross & Hoaken, 2010). For high secure forensic psychiatric settings, the benefits of CR may be twofold, given the offending history of many patients and the high prevalence of schizophrenia in this population (Thomson, Bogue, Humphreys, Owens, & Johnstone, 1997).

Cognitive Remediation

The term CR covers a broad array of different interventions. Some deliver treatment using pencil-and-paper methods (e.g. Sanchez et al., 2014) while others use computer based activities (e.g. Dickinson et al., 2010). Some deliver CR as a stand-alone therapy (e.g. Fisher et al., 2014) while others integrate CR with interventions designed to generalise neuropsychological gains to functional outcomes (e.g. Bowie, McGurk, Maudsley, Patterson, & Harvey, 2012). Some employ strategy-based approaches to circumvent cognitive deficits (e.g. Twamley, Vella, Burton, Heaton, & Jeste, 2012), while others use “drill and practice” methods to restore cognitive functioning (e.g. Bucci et al., 2013). Drill and practice approaches are generally based on the premise that improvements to performance on treatment activities will result in improvements to cognitive skills which

will in turn generalise to ‘functional capacity’, a construct encompassing the skills underpinning real-world functioning (Medalia & Saperstein, 2013). CR usually involves two or three sessions of training per week, with participants in CR studies completing an average of 32 hours of treatment over 17 weeks (Saperstein & Kurtz, 2013). It should be emphasised that there is considerable variability in the dose delivered in CR studies (Medalia & Choi, 2009) with some studies finding significant changes in cognitive functioning following fewer than 20 hours of training (e.g. McGurk, Mueser, & Pascaris, 2005)

Evidence base for CR

A meta-analysis by Wykes, Huddy, Cellard, et al. (2011) provides support for the effectiveness of CR in improving cognitive functioning and, in turn, psychosocial functioning. Studies also suggest that CR may lead to improvements in negative symptoms (Sanchez et al., 2014) and self-esteem (Garrido et al., 2013).

A meta-analysis looking specifically at computer-assisted cognitive remediation (CACR) also found that cognitive outcomes improved following treatment, however a lack of studies employing a functional outcome measure precluded an examination of the effect of CACR on psychosocial functioning (Grynszpan et al., 2011). The generalisation of cognitive gains to functional outcomes may be largely dependent on the delivery of a concurrent intervention targeting the skills underpinning functional capacity (Wykes et al., 2011; Gallagher, 2014) and may also be influenced by real-world opportunities to practice and develop these skills (Holshausen, Bowie, Mautsach, Patterson, & Harvey, 2014).

Despite the potential benefits of CR for a forensic population, there appear to be few studies in the peer-reviewed literature that explore the efficacy or acceptability of CR with a forensic setting. However, a recent study by (Rocha, Marques, Fortuna, Antunes, &

Hoaken, 2014) piloted CR with female prisoners and provided some preliminary evidence that CR may be effective with this population.

Although the empirical evidence appears to indicate CR is effective, the methodological quality of CR studies has been criticised (Gallagher, 2014) with higher quality studies often failing to support the efficacy of CR (e.g. Dickinson et al., 2010). As a result of these issues, there has been some reluctance to endorse CR as a recommended treatment for schizophrenia (e.g. NICE, 2009). Nonetheless, advocates for CR maintain that the methodological quality of studies does not bias outcomes and that the next phase of CR research should focus on implementation issues such as attrition rates and other assessments of acceptability (Wykes et al., 2011).

Acceptability studies

Few studies appear to have explicitly focused on acceptability. Wykes et al. (2011) point out that the average attrition rates from CR studies (11%; Saperstein & Kurtz, 2013) will not necessarily reflect the acceptability of CR or be applicable to clinical settings as payments are often made to participants in research trials. Furthermore, there is considerable variation in attrition across studies, with many finding rates notably above average, such as 48% in a study recruiting inpatients (Byrne et al., 2013) and 30% in a study delivering CACR in participants' homes (Fisher et al., 2014), suggesting treatment setting may have an influence on attrition.

Attention has turned to identifying other factors that may influence attrition rates in CR studies. Motivation has been identified as a key element in retaining participants in CR interventions, with intrinsic rather than extrinsic motivation thought to be most significant factor (Medalia & Choi, 2009; Saperstein & Kurtz, 2013). Twamley, Burton, & Vella (2011) explored the potential clinical, cognitive or demographic factors that may predict individuals dropping out from CR, after finding an attrition rate of 48% in their RCT.

Although they found no differences between those who dropped out during treatment and those who completed, they did find that participants who dropped out of their study before beginning treatment had lower levels of education than those who completed (Twamley et al., 2011).

Attrition from forensic interventions has been the subject of extensive research. This likely reflects the challenges involved in engaging antisocial individuals in treatment programmes (Wormith & Olver, 2002) which has contributed significantly to the lack of empirical evidence for psychological interventions with forensic psychiatric patients (Forensic Mental Health Matrix Working Group, 2011). A meta-analysis by Olver, Stockdale, & Wormith (2011) identified a wide range of factors that predict attrition from forensic interventions, including younger age; a longer sentence; lower scores on assessments of intelligence; a diagnosis of anti-social personality disorder (ASPD); a history of substance misuse; and a higher risk of future offending. Symptoms of psychosis have also been associated with higher attrition rates (Van Stelle, Blumer, & Moberg, 2004).

As with CR studies, significant attention has been paid in the forensic treatment literature to the subject of motivation, a key aspect in the successful delivery of psychological interventions with forensic psychiatric patients (Forensic Mental Health Matrix Working Group, 2011). Lower levels of motivation have been highlighted as another factor associated with higher attrition rates (Olver et al., 2011), however institutional treatment settings have been associated with lower attrition rates, possibly due to external motivating factors, such as early release (Olver et al., 2011).

Aims

In summary, CR appears to have the potential to provide significant benefits to high secure forensic psychiatric patients, however there may also be significant challenges faced in the implementation of CR in a forensic setting. The current study broadly aims to evaluate the

implementation of CACR in a high secure forensic psychiatric hospital to help inform service-based decisions about the use of CACR as a clinical intervention, as well as informing decisions about conducting further efficacy studies of CACR in this type of setting. The study will aim to explore the following research questions:

1. Can CACR be successfully implemented within a high secure forensic environment?

It is hypothesised that 1) the attrition rate will be similar to the average attrition rate in CR studies (11%; Saperstein & Kurtz, 2013); and 2) participants completing treatment will attend for a mean of 3 sessions per week, as planned in the treatment protocol (see Table 1 below for further details).

2. Are there significant differences between those who complete treatment and those who don't?

Based on the predictors of treatment attrition identified in the studies by Olver et al. (2011) and Van Stelle et al. (2004), it is hypothesised that in comparison to treatment completers, those dropping out of treatment either before or during treatment will: be younger; have had a longer stay in the hospital; score higher on a measure of risk of violence; score higher on measures of psychosis symptoms; and score lower on a measure of insight, a construct commonly covered in violence risk assessments (e.g. Webster, Douglas, Eaves, & Hart, 1997).

3. Is CACR associated with improvements to performance on treatment activities, as well as clinical and functional outcomes?

It is hypothesised that performance on treatment activities (i.e. CACR modules) will improve following CACR, along with scores on measures of functional capacity, negative symptoms and self-esteem. The effect of CACR on a routinely used measure of

psychological distress will also be explored. It is hypothesised that improvements will be sustained over a three month period.

Methods

Design

The study employed an uncontrolled pre/post-test design.

Participants

Participants were inpatients recruited from a high secure forensic psychiatric hospital. Due to the admission requirements of the hospital, all participants were male, aged 18 or over, and required conditions of special security to manage the risk of violence or sexual violence. While participating in CACR treatment, all participants continued to be offered the standard care and treatment available within the hospital. Treatment plans are tailored to each individual according to clinical need and may include medical, nursing, occupational therapy and other psychological interventions.

Participants were considered eligible for CACR if there was an indication that their cognitive functioning may have been reduced as a result of one or more of the following factors: a diagnosis of schizophrenia; a prior head injury; or diagnosis of alcohol or substance abuse. Participants were ineligible for treatment if they had a diagnosed or suspected neurological condition, or if they had any known cognitive deficits thought to significantly impair their functioning.

An a-priori power calculation was conducted to determine the sample size required for the study. Given that improving day-to-day functioning is the ultimate goal of CACR, the effect size found for functional outcomes in the meta-analysis by Wykes et al. (2011) was used for the calculation ($E.S. = 0.42$). For a repeated-measures within-groups ANOVA, using an alpha level of 0.05 and power of 80%, 42 participants would be required.

Measures

Baseline measures

In addition to the measures outlined below, baseline demographic data was obtained from participants' files.

Cognitive functioning: The MATRICS Consensus Cognitive Battery (MCCB; Nuechterlein et al., 2008) covers the core neuropsychological domains thought to be affected in individuals diagnosed with schizophrenia. For the purposes of this study, the composite t-score covering performance on all 10 subtests of the MCCB was used to assess participants' baseline cognitive functioning. The MCCB has demonstrated good internal consistency (Cronbach's $\alpha = 0.76$; Burton et al., 2013) and good test-retest reliability for the composite score (intraclass correlation coefficient = 0.90; Nuechterlein et al., 2008). A copy of the MCCB materials is not included in appendices due to copyright restrictions.

Risk of violence: The Historical, Clinical and Risk Management-20 (HCR-20; Webster et al., 1997) covers static (historical) and dynamic (clinical; risk) factors that have been shown to predict future violence. Each of the 20 items is rated on a 3-point scale. In this study, scores for each subscale were used (historical, clinical and risk) along with the total score. The HCR-20 has been shown to have excellent internal consistency (Cronbach's $\alpha = 0.95$; Belfrage, 1998) and good test-retest reliability (intraclass correlation coefficient = 0.80; Douglas & Webster, 1999). A copy of a HCR-20 scoring document can be found in Appendix 2.2.

Symptoms of psychosis: The abbreviated version of the Psychosis Evaluation Tool for Common Use by Caregivers (PECC; Hert et al., 2002) evaluates 8 symptom items on a 7-point scale. Symptoms are grouped to provide scores across three factors: positive (hallucinations, delusions, unusual thought content, grandiosity), negative (blunted affect), depressive (depression, feelings of guilt, somatic concerns). Scores for the positive and negative scales were used for this study. Although the full version of the PECC has been shown to have good convergent validity (Hert et al., 2002), other psychometric

characteristics have not been reported in the literature. A copy of the PECC scoring guidance document can be found in Appendix 2.3.

Insight: The Behavioural Status Index (BEST; Woods, Reed, & Robinson, 1999) covers 150 items, rated on a 5-point scale. It aims to assess performance on a range of life skills. For the purposes of this study, only the total score for the 20-item 'Insight' sub-scale was used which aims to measure individuals' insight into the nature of their problems and their own role in the development of these problems. The BEST has been shown to have good test-retest reliability (intraclass correlation coefficient = 0.84; Woods et al., 1999) however the internal consistency of the measure has not been adequately reported. A copy of the items that constitute the BEST Insight scale can be found in Appendix 2.4.

Outcome measures

Functional capacity: The University of California San Diego Performance Based Skills Assessment (UPSA; Patterson, Goldman, McKibbin, Hughs, & Jeste, 2001) tests a range of skills related to independent community living (household tasks; communication; finance; transportation; planning recreational activities) and provides an overall score out of 100. A recent study has indicated that individuals' scoring 75 out of 100 are likely to be capable of independent living (Mausbach et al., 2008). Minor adaptations were made across a range of areas to make the UPSA more culturally relevant to UK-based participants (e.g. changing the currency from dollars to pounds) and to ensure the items required for assessment tasks complied with hospital security regulations. All amendments were made following discussions between members of the research team to ensure that changes were kept to a minimum. The original UPSA manual can be found in Appendix 2.5, while the amended version is in Appendix 2.6. The UPSA has been shown to have good test-retest reliability (intraclass correlation coefficient = 0.93; Harvey, Velligan, & Bellack, 2007) however the internal consistency of the measure has not been reported.

Negative Symptoms: The Clinical Assessment Interview for Negative Symptoms (Version 1) (CAINS; Forbes et al., 2010) is a measure of the negative symptoms of psychosis. The 13 items of the CAINS are evaluated on the basis of a semi-structured clinical interview. Scores are derived on a scale measuring motivation and pleasure, and a second subscale measuring expression, which can be combined into a total score (Horan, Kring, Gur, Reise, & Blanchard, 2011). For the purposes of this study, the subscale scores will be reported rather than the total score as these are thought to represent two distinct treatment targets (Kring, Gur, Blanchard, Horan, & Reise, 2013). The CAINS has been shown to have good internal consistency (Cronbach's $\alpha = 0.76$; Kring et al., 2013) and good test-retest reliability (intraclass correlation coefficients = 0.93 for motivation and pleasure subscale and 0.77 for expression subscale; Kring et al., 2013). A copy of the CAINS interview schedule and scoring guide can be found in Appendix 2.7.

Self-Esteem/Self-Image: The Self-Image Profile for Adults (SIP-AD; Butler & Gasson, 2006) is a 30 item self-report scale, measuring both self-esteem (SIP-SE) and self-image (SIP-SI). For each item (e.g. 'optimistic'), participants provide responses on how they see themselves, as well as how they would like to be. The SIP-AD has been shown to have excellent internal consistency (Cronbach's $\alpha = 0.90$; Butler & Gasson, 2006) however test-retest reliability has not been reported in the literature. A copy of the SIP-AD is not included in appendices due to copyright restrictions.

Psychological distress: The Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE; Evans et al., 2002) is a 34 item self-report questionnaire designed to measure problem severity and change following psychological interventions. Responses are marked on a 5-point scale from "not at all" to "most or all of the time". It covers four different domains (subjective well-being, problems/symptoms, life functioning and risk to self and others), however the total score was used for this study. The CORE has been shown to have excellent internal consistency (Cronbach's $\alpha = 0.94$; Evans et al., 2002) and good test-rest reliability (intraclass correlation coefficient = 0.90; Evans et al., 2002). A copy of the CORE questionnaire can be found in Appendix 2.8.

Other measures

Treatment adherence/Performance on treatment tasks: The CogniPlus system automatically collects data on each CACR session, including the date and length of the session, as well as the difficulty level achieved on each task.

Participant feedback: A feedback questionnaire was created for the purposes of the study to explore participants' experiences of the treatment. This can be found in Appendix 2.9. It included six questions about their enjoyment of each of the CogniPlus modules, rated from one to five on a Likert scale (1=did not enjoy at all; 5=really enjoyed). 5 other Likert scale questions covered participants' views on: their enjoyment of the training (1=did not enjoy at all; 5=Really enjoyed); how interesting they found it (1=not at all interesting; 5=highly interesting); their perception of improvements to both their memory and attention ('Do you feel that the training has improved your [memory/ability to pay attention]; 1=no, not at all; 5=yes, lots); and how likely they would be to recommend it to others (1=would definitely not recommend; 5=would definitely recommend). It also included six open-ended questions ('What did you like about the training'; 'What are the good things that you will take away from the training'; how have you benefited from the training'; 'what did you dislike about the training'; 'what did you find difficult'; 'can you think of anything to make the training better').

Procedure

The study involved two phases. The initial 'research' phase received ethical approval from South East Scotland Research Ethics Committee and the local research committee. A copy of the documents confirming ethical and hospital approval for the research phase can be found in Appendix 2.10. After agreeing to speak to researchers following a discussion with their responsible medical officer, participants provided written informed consent to participate in the study. A copy of the consent form and participant information sheet can be found in Appendix 2.11.

Following the completion of the research phase, the intervention was included as part of the set of psychological therapies offered within the hospital, with participants referred for CACR by the clinical team responsible for their care and treatment. Approval was given by South East Scotland Research Ethics Committee, the local research committee and the University of Edinburgh for a service evaluation of CACR to take place (see Appendix 2.12 for the relevant documents). Table 1 highlights modifications made between the research and service evaluation phases; these are discussed further below.

Treatment

CogniPlus is a recently developed CACR package that includes a number of key features designed to be engaging for participants, with the aim of increasing motivation and treatment adherence (Schuhfried, n.d.). These include the use of real world-tasks and scenarios; the use of computer-game style graphics; and the calibration of task difficulty levels in response to participant performance to ensure tasks are never too easy or too difficult (Schuhfried, n.d.). Although there is currently little current evidence for the efficacy of CogniPlus, it has been designed as an advancement to the same developer's Rehacom system which has been shown to be effective in improving cognitive functioning in a number of studies (e.g. d' Amato et al., 2011).

Table 1 above indicates the treatment schedule for both the research and service evaluation arms of the study, with Table 2 providing a description of the neuropsychological domain targeted by each CogniPlus module. In both arms, treatment was planned to consist of 3 phases of equal length consisting of three one-hour sessions per week. Each session involved 2 or more different modules, with equal time spent on each module during a session. The initial phase targeted different aspects of attention, as improvements in attention are thought to facilitate improvements in other aspects of patients' cognitive functioning (López-Luengo & Vázquez, 2003). Subsequent phases continued to target attention while also targeting executive functioning and working memory.

Table 1: A comparison of the Research and Service Evaluation arms of the study

	Research	Service Evaluation
Treatment schedule	3 sessions per week over 14 weeks	3 sessions per week over 10 weeks
Treatment session plan:*		
Phase 1	ALERT; VIG (14 sessions)	ALERT; VIG; SELECT (10 sessions)
Phase 2	ALERT; FOCUS; NBACK; PLAND (14 sessions)	ALERT; FOCUS; NBACK (10 sessions)
Phase 3	ALERT; SELECT; NBACK (14 sessions)	ALERT; NBACK; PLAND (10 sessions)

*See Table 2 for details of modules

Table 2 – Neuropsychological domain targeted by each CogniPlus module

Module name	Neuropsychological domain
ALERT	Attention: alertness
VIG	Attention: vigilance
SELECT	Attention: selective
FOCUS	Attention: focused
NBACK	Working memory
PLAND	Executive functioning

Assessments

All baseline measures were obtained from participants' files and had been completed by trained clinicians as part of the routine clinical work of the hospital, with the exception of the MCCB which was used specifically for the purposes of this study. HCR-20 assessments were completed by the multi-disciplinary team responsible for participants' care, while the BEST and PECC were completed by participants' nursing key-worker.

Outcome measures and the MCCB were completed by various members of the psychological therapies team (a trainee clinical psychologist, a nurse practitioner, two assistant psychologists and a PhD student). With the exception of the CAINS, assessors were trained in the administration of outcome measures by the consultant neuropsychologist overseeing the project. Two assessors were trained to administer the CAINS (the trainee clinical psychologist and the PhD student), which involved rating videos of interviews provided by the developers of the tool. Although "gold-standard" ratings of these videos were also provided, assessors' scores were not formally compared to these. It should also be noted that inter-rater reliability and rater drift were not assessed for any of the outcome measures. Supervision was provided to all assessors, either in the normal course of their clinical work or by the consultant neuropsychologist.

Outcome measures were administered before and after treatment, with follow-up assessments planned for three, six and 12 months after the completion of post-treatment assessments. Follow-up assessments were only partially completed at the time of submission (see Figure 1 below for details). Demographic and other baseline information was taken from routinely collected information in participants' case notes.

Data analysis

Preliminary analyses

All data were assessed for normality and skewness using the Kolmogorov-Smirnov test and the skewness statistic. Independent samples t-tests/Mann-Whitney tests were used to

assess any differences between the research and service evaluation groups in terms of the number of hours of CACR completed, both overall and for each module. Due to the small sample size and the exploratory nature of the study, a p-value of 0.05 was used as a threshold for significance across all tests.

1. Can CACR be successfully implemented within a high secure forensic environment?

Attrition rates were calculated, both for those dropping out before completing baseline assessments and those dropping out during treatment. Participants were considered to have dropped out if they failed to complete at least 20 hours of CACR or if they failed to complete at least one session from each planned phase of their treatment.

To assess treatment adherence, means and standard deviations were calculated for the number of sessions and hours of CACR completed, as well as the number of weeks in treatment and the average number of sessions completed per week. Calculations were completed for the intention to treat sample (ITTS; i.e. all those who completed baseline assessments), as well as for those who completed treatment.

Mean scores were calculated for each of the Likert scale questions in the feedback questionnaire.

2. Are there significant differences between those who complete treatment and those who don't?

Effect sizes (Cohen's d) were used to compare those who started treatment and those who didn't across demographic data and each of the baseline measures outlined above. The

same comparisons were made between those who completed treatment and those who started but dropped out, with the addition of comparisons of baseline scores for each of the outcome measures. Differences were considered significant if the effect size was greater than 1.

3. Is the treatment associated with improvements to performance on treatment activities, as well as clinical and functional outcomes?

An intention-to-treat analysis was employed to evaluate the performance of the ITTS on the CogniPlus modules, as well as each of the outcome measures. Missing data was addressed using the Last Observation Carried Forward (LOCF) method. One-way repeated measures ANOVAs and Friedman's tests were used to evaluate change over time. Effect sizes were calculated using Cohen's d (Cohen, 1992) for all outcome measures, comparing baseline scores to post-treatment scores and to follow-up scores.

Due to variability in the number of sessions completed by participants, analyses of performance on treatment activities were based on the treatment plan for the service evaluation group. This allows an analysis of performance across a typical treatment plan. Where participants completed fewer sessions, a LOCF method was used. Clearly, it was only possible to include participants in these analyses if they had completed at least one session on the module. Due to the initial process of calibrating difficulty levels to participant ability, analyses of performance on treatment activities were repeated with the first session omitted, as the difficulty level achieved on this session may reflect the calibration process rather than participants' performance.

Results

Demographic details of the participants are summarised in Tables 3 and 4. Assessments of normality and skewness indicated that scores on the following measures were not normally distributed: length of admission; HCR-20 (total score only); UPSA scores at baseline; SIP scores at post-treatment and 3-month follow-up (but not baseline); and difficulty levels on ALERT, FOCUS, VIG, NBACK modules. No significant differences were found between the hours of treatment completed by participants in the two phases of the study (research phase and service evaluation phase) therefore results were combined for subsequent analyses. Figure 1 provides a CONSORT diagram summarising recruitment and retention within the study. Follow-up data was still being collected at the time of writing and six and 12-month data was omitted from analyses due to the low number of assessment completed.

Participants were split into three groups according to their engagement in CACR. Individuals dropping out before completing baseline assessments were classed as 'Refusers'; those dropping out after baseline assessments were completed were classed as 'Dropouts'; with all others classed as 'Completers'. In addition, the combination of the 'Dropouts' and 'Completers' was defined as the 'intention-to-treat sample' (ITTS).

1. Can CACR be successfully implemented within a high secure forensic environment?

Recruitment

Overall, 27 individuals agreed to take part in the intervention. Seven of those dropped out before pre-treatment assessments were completed (constituting the 'Refusers' group), leaving 20 who started the treatment and constituted the intention-to-treat sample ('ITTS'). Reasons for patients refusing to start treatment can be found in Figure 1.

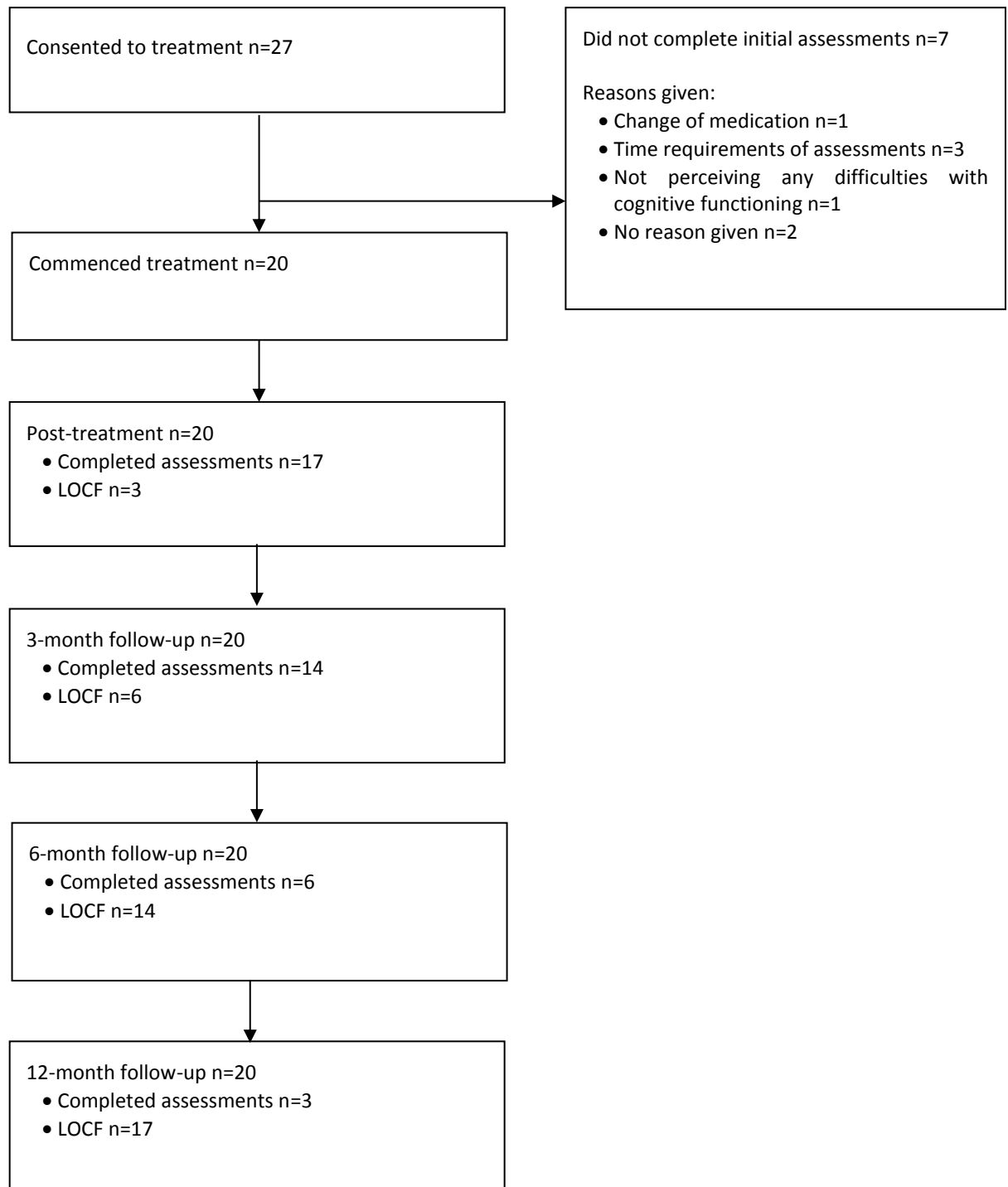
Table 3 - Baseline data and comparisons between Completers and Drop-outs

	Completers (n=13)	Drop-outs (n=7)	Effect Size
	Mean (SD) or %	Mean (SD) or %	Cohen's d
Age	41.07 (12.87)	31.66 (9.01)	0.85
Length of admission	5.42 (7.50)	2.39 (2.13)	0.55
Baseline MCCB score	29.33 (10.22)	23.67 (10.27)	0.55
ASPD diagnosis	23.08%	14.29%	-
Substance Abuse	76.92%	100%	-
Primary Diagnosis			
<i>Schizophrenia</i>	69.23%	100%	-
<i>Schizoaffective</i>	7.69%	0%	-
<i>Bipolar disorder</i>	7.69%	0%	-
<i>Delusional disorder</i>	7.69%	0%	-
<i>Alcohol psychosis</i>	7.69%	0%	-
HCR-20 Historical	12.67 (4.27)	14.43 (4.16)	0.42
HCR-20 Clinical	4.92 (1.68)	6.00 (1.73)	0.63
HCR-20 Risk	5.50 (1.45)	5.00 (1.73)	0.31
HCR-20 Total	28.92 (21.44)	25.43 (5.91)	0.22
PECC negative	2.62 (1.67)	2.86 (2.12)	0.13
PECC positive	7.46 (4.50)	11.57 (6.50)	0.74
BEST Insight	70.54 (18.74)	67.57 (17.62)	0.16
CAINS Motivation	14.08 (9.97)	13.86 (8.17)	0.02
CAINS Expression	5.69 (3.66)	6.00 (4.62)	0.07
CAINS Total	19.77 (12.94)	19.86 (11.71)	0.01
SIP Self-image	97.38 (35.13)	109.29 (32.19)	0.35
SIP Self-esteem	57.15 (27.38)	47.57 (21.96)	0.39
UPSA	69.62 (15.65)	78.57 (11.34)	0.65
CORE	31.38 (20.66)	27.43 (21.55)	0.19

Table 4 - Baseline data and comparisons between Completers and Refusers

	Completers (n=13)	Refusers (n=7)	Effect Size
	Mean (SD) or %	Mean (SD) or %	Cohen's d
Age	41.07 (12.87)	49.63 (7.98)	0.80
Length of admission	5.42 (7.50)	13.68 (6.94)	1.14
ASPD diagnosis	23.08%	42.86%	-
Substance Abuse	76.92%	71.43%	-
Primary Diagnosis			
<i>Schizophrenia</i>	69.23%	85.71%	-
<i>Schizoaffective</i>	7.69%	14.29%	-
<i>Bipolar disorder</i>	7.69%	0%	-
<i>Delusional disorder</i>	7.69%	0%	-
<i>Alcohol psychosis</i>	7.69%	0%	-
HCR-20 Historical	12.67 (4.27)	15.20 (2.78)	0.70
HCR-20 Clinical	4.92 (1.68)	6.80 (1.79)	1.08
HCR-20 Risk	5.50 (1.45)	7.00 (2.16)	0.82
HCR-20 Total	28.92 (21.44)	48.00 (35.16)	0.66
PECC negative	2.62 (1.67)	2.29 (0.95)	0.24
PECC positive	7.46 (4.50)	9.14 (2.91)	0.44
BEST Insight	70.54 (18.74)	49.43 (7.23)	1.48

Figure 1 - CONSORT Diagram



Retention and treatment adherence

Of the ITTS, seven participants prematurely ended treatment (constituting the 'Drop-outs' group). Reasons given were: finding the treatment tedious and/or struggling to identify any potential benefits (n=4); a deterioration in mental state (n=2); and finding it difficult to comprehend task instructions (n=1). The remaining participants constituted the 'Completers' group.

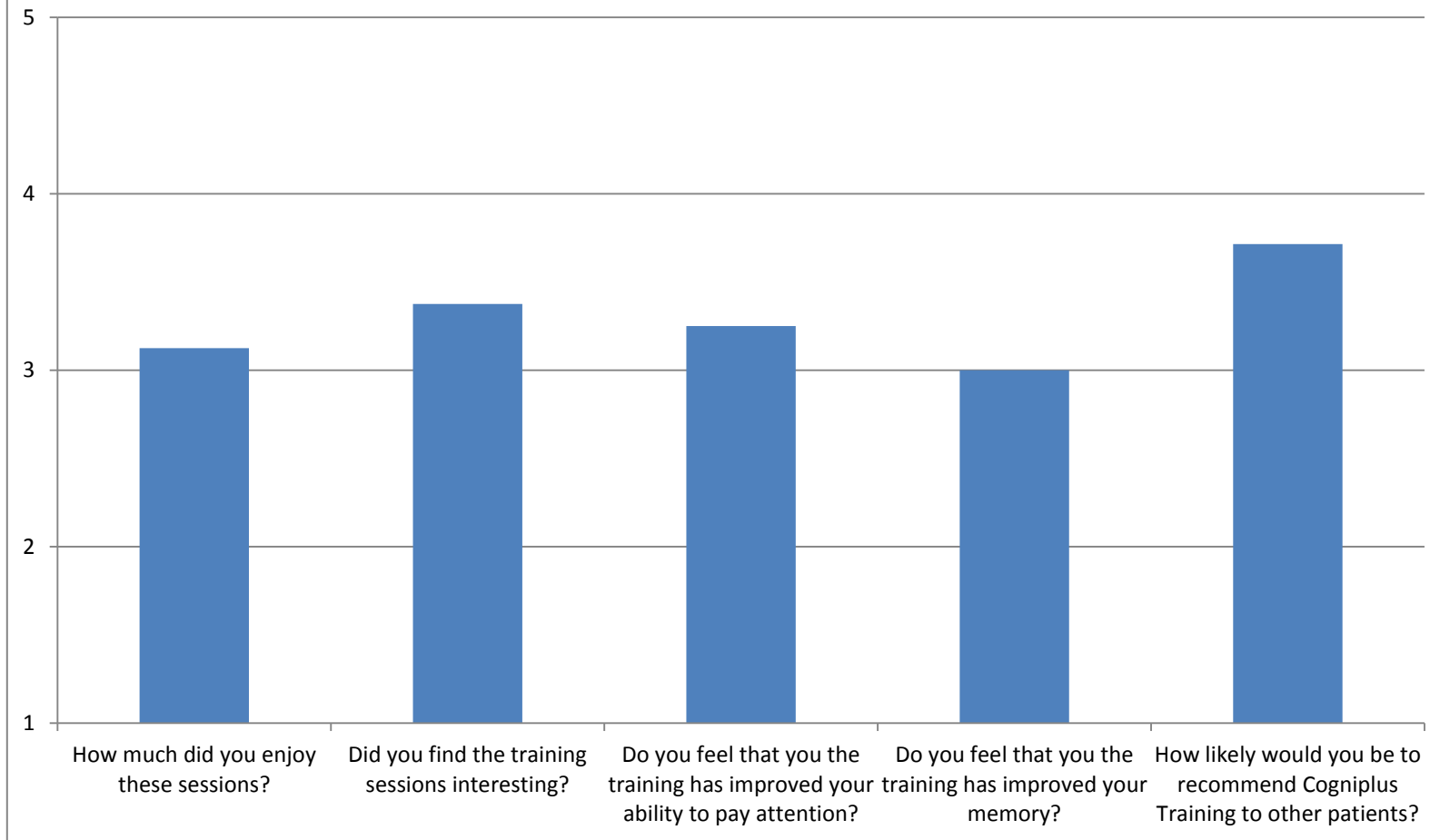
Participants in the ITTS completed a mean of 0.82 hours (SD=0.20) of treatment per session, with a mean of 1.77 sessions (SD=0.76) completed per week. In total, the mean number hours of treatment completed by participants in the ITTS was 21.69 hours (SD=13.09) in a mean of 24.80 sessions (SD=14.16), over a mean of 11.96 weeks (SD=6.10).

The Completers group managed a mean of 0.90 hours (SD=0.08) per session, with a mean of 2.09 sessions (SD=0.57) completed per week. In total, the mean number of hours of treatment completed by this group was 30.38 (SD=5.28), in a mean of 34.00 sessions (SD=6.71), over a mean of 15.32 weeks (SD=4.01).

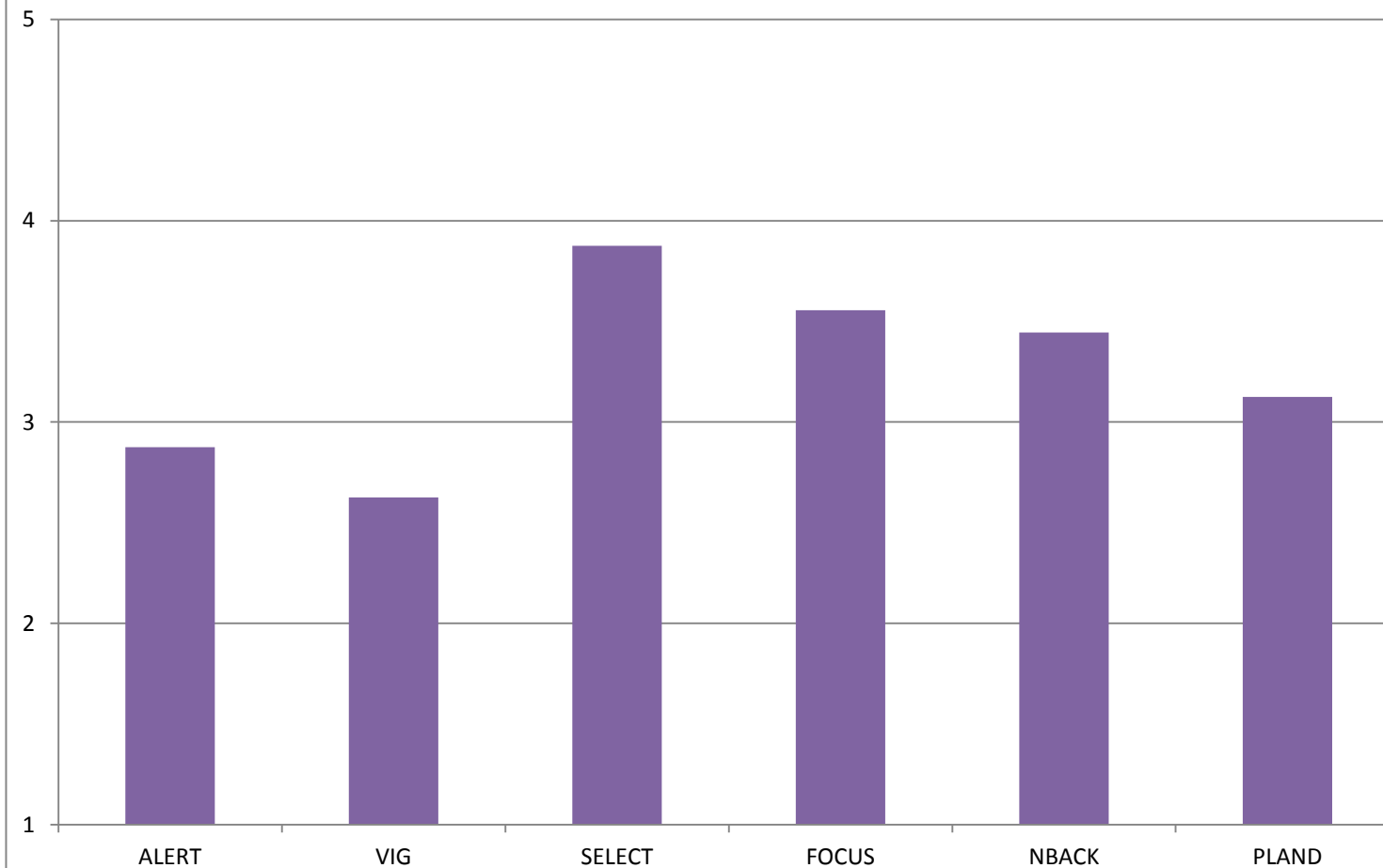
Feedback

The feedback form was completed by nine participants from the service evaluation arm of the study, a response rate of 69.23%. As participants were able to return this anonymously through the hospital internal mailing system, it is not possible to identify the proportion of forms returned by Completers and Dropouts. Figure 2 shows mean scores on questions about participants' perceptions of the intervention as a whole, while Figure 3 contains participants' ratings of each module. All questions were scored on a 5-point Likert scale, with higher scores indicating a more positive response.

Figure 2: 5-point Likert scale questions assessing participants' overall perceptions of CogniPlus



**Figure 3: 5-point Likert Scale Questions Evaluating
Participants' Enjoyment of Each Treatment Activity**



In response to the open-ended questions, participants replied with a number of positive comments. Two respondents remarked on aspects of training that they liked; one indicated that he enjoyed the novelty of the intervention (“It helped me to focus on something new”), while another referred to the diversity of modules (“[I enjoyed the] different varieties of tasks - different subjects”). When asked about any improvements following training, two participants mentioned perceived improvements to aspects of cognitive functioning (“I think I can focus on problems and my memory and alertness are improved”; “More alert, more vigilant... can see an improvement [in my memory]”) while another seemed to focus more broadly on their mental health (“State of mind”).

A number of less positive comments were also included in the feedback, with five respondents mentioning that the intervention was “tedious”, “boring” or “went on too long”, with specific mention made of the VIG module. Three respondents indicated that they hadn’t noticed any improvements following CACR.

Only one participant gave advice on how the treatment could be improved, commenting “I think rather than [VIG] it would be more therapeutic to do a task 1-1 with a psychologist”.

2. Are there significant differences between those who complete CACR and those who don’t?

Baseline comparisons can be seen in Tables 3 and 4. Those who completed treatment have been compared firstly to those who dropped out, and secondly to those who refused to start treatment.

No significant differences were found between Completers and Drop-outs. However, there were significant differences between Completers and Refusers in terms of the length of admission, scores on the BEST Insight scale, and scores on the Clinical sub-scale of the HCR-20.

3. Is CACR associated with improvements to performance on treatment activities, as well and clinical and functional outcomes?

Treatment activities

Figure 4 shows the mean difficulty level achieved on each module at each session by participants in the ITTS. This is based on the 30 session treatment plan used in the service evaluation phase.

Results of ANOVAs/Friedman's tests on the treatment activities found significant differences over time in terms of difficult ratings for ALERT ($\chi^2(29, n=20) = 64.24, p<0.01$); SELECT ($F(1.76, 29.86) = 11.76, p<0.01$), FOCUS ($\chi^2(9, n=15) = 21.10, p=0.01$) and PLAND ($F(1.78, 23.07) = 14.78, p<0.01$). No significant differences over time were found for VIG ($\chi^2(9, n=19) = 13.71, p=0.13$) or NBACK ($\chi^2(19, n=14) = 13.31, p=0.82$). When the analyses were repeated with the initial calibration session removed, both ALERT ($\chi^2(27, n=20) = 21.75, p=0.05$) and FOCUS ($\chi^2(8, n=15) = 8.82, p=0.36$) no longer demonstrated any significant differences over time.

Clinical and Functional Outcomes

Table 5 summarises the post-treatment effects for each of the outcome variables used. ANOVAs/Friedman's tests indicate that, over time, participants improved significantly on the Motivation and Performance sub-scale of the CAINS ($F(1.41, 26.77) = 5.65, p=0.02$) and the self-esteem scale of the SIP ($\chi^2(3, n=20) = 7.77, p=0.05$). Effect sizes post-treatment were small for the significant results, however improvements to the Motivation and Performance sub-scale of the CAINS appears to have been largely maintained at the 3-month follow-up stage. Post-hoc analyses did not find any significant differences between time points, perhaps due to the small sample size used in the study.

Figure 4: Mean Difficulty Level Achieved on CogniPlus Modules at Each Session Across 30 Session Treatment Plan

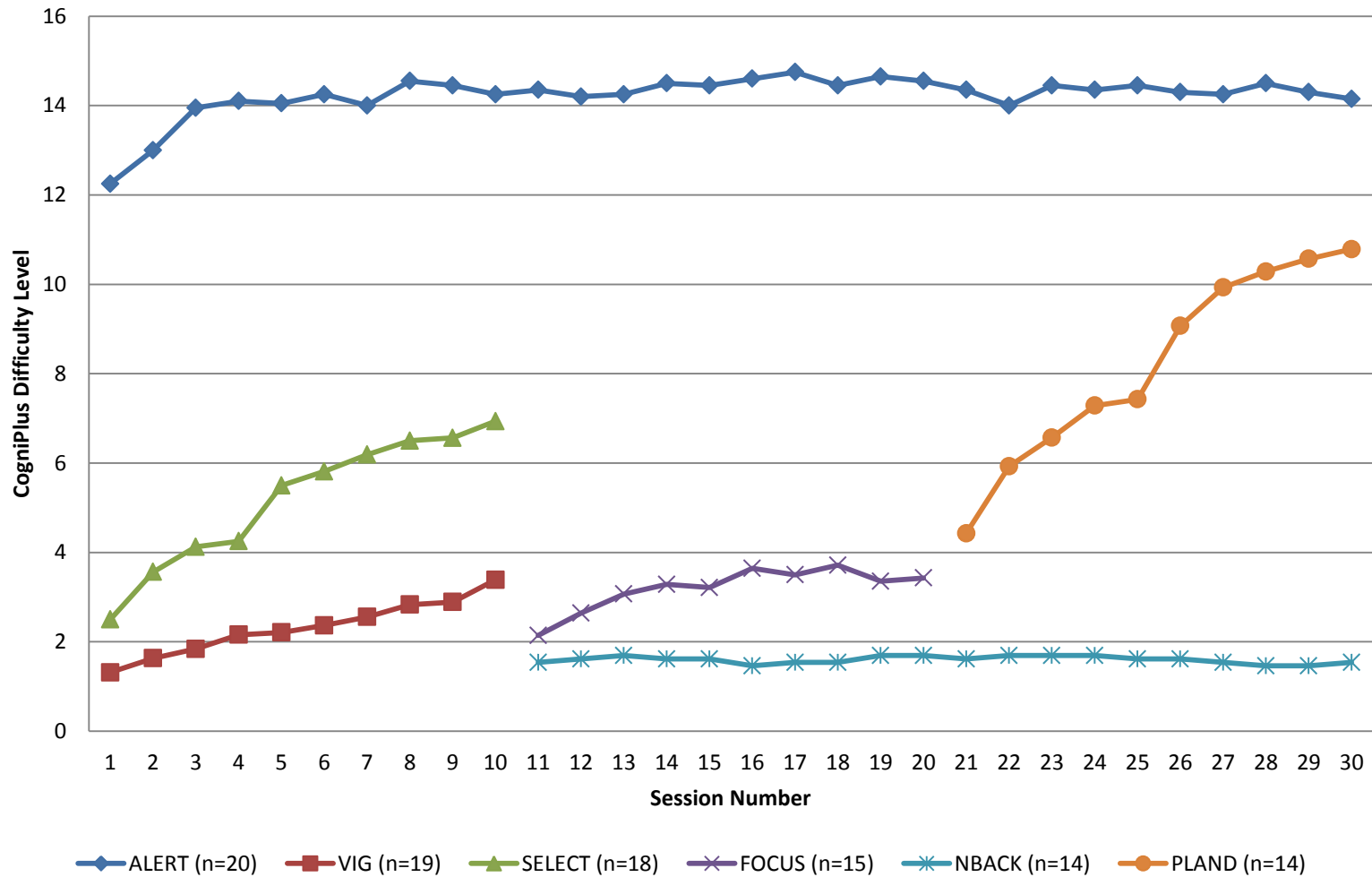


Table 5 - Outcome measures: means, standard deviation, ANOVA/Friedman's tests, and effect sizes for ITTS

Measure	<u>Pre-treatment</u>		<u>Post-treatment</u>		<u>3-month follow-up</u>		<u>ANOVA/ Friedman's*</u>			<u>Effect Size (Cohen's d)</u>	
	Mean	SD	Mean	SD	Mean	SD	F/ χ^2	df	p	Post	3-month
UPSA	72.75	14.65	74.85	11.67	74.10	11.67	1.73*	2	0.42	0.16	0.10
CAINS											
<i>Motivation</i>	14.00	9.16	10.40	7.75	9.45	7.42	7.42	1.19	0.01	0.42	0.55
<i>Expression</i>	5.80	3.90	4.75	3.88	5.10	3.57	2.00	2	0.15	0.27	0.19
SIP											
<i>Self-image</i>	101.55	33.77	109.35	27.46	104.10	31.30	2.13*	2	0.34	0.25	0.08
<i>Self-esteem</i>	53.80	25.45	45.95	22.09	47.35	19.15	6.13*	2	0.05	0.33	0.29
CORE	30.00	20.50	25.60	19.27	27.00	19.53	1.60	2	0.21	0.22	0.15

*Friedman's test used due to non-parametric data

Discussion

CACR has the potential to offer significant benefits to forensic psychiatric patients and the current study provides an evaluation of the implementation of CACR in a high secure forensic setting. The broad aims were to explore acceptability by looking at attrition rates and treatment adherence data; identify factors that may predict treatment attrition; and generate preliminary outcome data.

Over 50% of participants dropped out from the study either before or during treatment, compared to an average attrition rate in CR interventions of 11% (Saperstein & Kurtz, 2013). Roughly similar attrition rates have been found in other studies conducted across a range of treatment settings (e.g. Twamley et al., 2011; Fisher et al., 2014; Byrne et al., 2013), however this level of attrition has been characterised as “a significant obstacle” in previous research (Twamley et al., 2011). Those who dropped out during treatment were indistinguishable from completers, a finding similar to that of Twamley et al. (2011) which indicates prematurely ending treatment cannot be explained demographic, clinical, and risk factors. As a result, the only data available to explain attrition are feedback about the treatment itself, as well as self-reported reasons for dropping out. The consistent message from these sources of data would appear to be that the treatment was perceived as being “boring”, “tedious” and “too long”, with over half the respondents to the feedback questionnaire describing the treatment in this way, and over half of those who dropped out of treatment explaining their decision using broadly similar terms.

With regards to adherence, participants received a lower ‘dose’ of treatment than planned, with the treatment completers only managing an average of two sessions per week rather than the planned three sessions. Nonetheless, the frequency and total amount of treatment received by the ITTS exceeds that which has been shown to be sufficient for change in previous studies (e.g. McGurk et al., 2005). So while it would appear that participants find it difficult to adhere to the treatment protocol, the evidence would suggest it is possible to deliver a potentially sufficient amount of treatment in a high secure

setting. However, despite the adequate dose of CACR received, there was little evidence of improvement on two of the six therapy tasks. Furthermore, two additional therapy tasks failed to show any improvements when the initial calibration sessions were removed from analyses. These results are also reflected in scores on the UPSA outcome measure, which failed to demonstrate any gains post-treatment. Although there were post-treatment improvements to scores of self-esteem and negative symptoms, it is of course possible that these relate to non-specific treatment effects rather than the effects of CACR.

In summary, the evidence suggests that most patients will drop-out at some stage in the recruitment and treatment process; that those who do go on to complete treatment don't adhere well to the treatment protocol; and that participants generally don't appear to improve their performance on treatment activities or functional outcome measures, despite receiving a potentially adequate dose.

Why such a poor outcome?

The lack of any improvement on treatment activities could potentially relate to a number of different factors, including floor effects on the treatment activities or perhaps simply that CogniPlus itself is not effective. However, participants' consistent feedback that treatment was "boring" may also be an important factor in the failure to find any significant improvements to treatment activity performance and UPSA scores. It is possible that this undermined participants' motivation to engage in, and benefit from, treatment.

Medalia & Choi (2009) highlight the importance of motivation in predicting outcomes in CR and suggest that finding a task "interesting and engaging" are the primary features of intrinsic motivation. They also stress that extrinsic motivators can have a negative impact on learning (Medalia & Choi, 2009). The combination of an intervention perceived as "boring" and a forensic treatment setting where many of the motivators for individuals to engage in treatment may be external (e.g. the goal of moving to lower levels of security;

Olver et al., 2011) may result in significantly lower levels of motivation to engage in CACR, negating some of the inherently motivating aspects of CogniPlus. This may help to explain both the poor adherence to the treatment schedule, as well as the lack of improvement across the therapy activities. A recent review of the CR literature lists a range of different approaches that may help address motivational issues, such as relating the remediation of cognitive deficits to the attainment of specific intrinsic and extrinsic goals and rewards that are meaningful to the participant (Saperstein & Kurtz, 2013). These ideas and principles may provide a guide for adapting the delivery of CACR in high secure forensic settings to include a range of motivation-enhancing strategies.

Is functional capacity an appropriate treatment target in a high secure hospital?

While these results may be disappointing, the use of CACR to target improvements in functional capacity may not be appropriate in a high secure forensic environment, due to patient characteristics as well as service related factors.

One striking finding from this study is that the mean score on the measure of functional capacity for the ITTS very close to the threshold that would predict the ability to live independently within the community (Mausbach et al., 2008). A further look at individual scores suggests that the majority of participants in the ITTS had a baseline functional capacity score above this threshold and that only two participants scored more than one standard deviation below. Although it is possible that there are cultural differences in the threshold required for independent living, it is clearly important that interventions are formulation driven and responsive to individual need (Forensic Mental Health Matrix Working Group, 2011), and as such it should be established that individuals have a functional capacity deficits before engaging in a treatment where this is a primary target of the intervention.

The opportunity to practice functional skills in a real-world setting has been noted to be a crucial bridge between functional capacity and real-world functioning (Holshausen et al., 2014). As such, high secure psychiatric clinics may be an inappropriate setting to target improvements in daily functioning, not only due to the lack of opportunities for practice but also due to the fact that many patients will move to lower levels of security before moving back to the community (Forensic Mental Health Matrix Working Group, 2011). If CACR aims to improve functioning, it would make sense for CACR to be delivered in advance of a planned move to the community, in conjunction with an intervention designed to directly help the development of functional skills which is thought to facilitate the generalisation of cognitive improvements (Gallagher, 2014).

Despite these reservations, it is important to emphasise that CACR delivered in a forensic setting has possible benefits beyond improvements to functional capacity. As mentioned in the introduction, CACR has the potential to contribute towards risk management (O'Rourke, 2013) and to improve outcomes of other psychological interventions (Ross & Hoaken, 2010), while the improvements to negative symptoms and self-esteem that were found in this study point to potential benefits for CACR that are unrelated to functional capacity. It will be important for future research to be conducted into these alternative treatment targets for CACR in high secure setting.

Recommendations

The results of this study lead to a number of recommendations:

1. Motivational deficits appear to be a problem common to both CR interventions and forensic interventions more generally. The clinical implementation of CACR in high secure forensic settings should incorporate a range of appropriate motivation enhancing strategies.
2. Future research should explore the role of CACR in high secure forensic settings for enhancing outcomes of other psychological interventions and contributing towards risk

management. Studies should also assess the hypothesised effect of motivational deficits on attrition, adherence and outcomes.

3. Where CACR aims targets improvements to functional outcomes in a forensic population, it should be delivered at lower levels of security, when individuals have regular opportunities to practice functional skills in real-world settings. It should also be delivered in conjunction with an intervention explicitly targeting the development of functional capacity. A deficit in functional skills should be a criterion for treatment eligibility.

Limitations

Statistical power is limited by the small sample size, increasing the risk of Type II errors. It is also possible that the risk of Type I errors was increased due to the number of comparisons made. The reliability of outcome measures may have been undermined by a number of factors, including the omission of an assessment of inter-rater reliability and the failure to ensure assessors' scores on CAINS training assessments were comparable to "gold standard" ratings. The reliability of assessments over the course of the study was also not monitored and it is possible that the significant effects identified in the study reflect rater drift. Assessors were not blinded, which may have affected outcomes, particularly those requiring significant clinical judgement such as the CAINS. Reasons for attrition may differ between the research and service evaluation arms of the study, which was not explored. The intervention did not include a control group, therefore the significant effects found cannot be confidently attributed to CACR itself. The use of LOCF may be an inappropriate way of dealing with missing data and can result in an overly conservative measure of effects. The participants had a range of diagnoses therefore outcomes cannot be generalised to specific diagnostic categories. This study does not cover neuropsychological outcomes which limits the ability to draw conclusions about the efficacy of CACR. Despite the prominence of motivational issues within the CR and forensic literature, the effect of motivation was not explored in the study.

It should be noted that many of the limitations outlined above reflect the challenges and restrictions of the clinical setting and client group. These challenges and restrictions are recognised as factors that have generally limited the development of evidence for psychological therapies delivered to forensic psychiatric patients (Forensic Mental Health Matrix Working Group, 2011).

Conclusion

Motivational deficits may have undermined the outcomes of this study and it will be important to ensure the delivery of CACR in forensic psychiatric settings is designed to incorporate strategies for enhancing motivation. In addition, using CACR to target functional outcomes may be inappropriate within a high secure forensic setting. As a result, the role of CACR as in managing risk and enhancing the outcomes of other interventions should be explored.

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Appendix 2.2 – HCR-20

HCR-20 ITEM DESCRIPTIONS FORM

Historical:

H1. Previous Violence

Violence is defined as **actual, attempted or threatened harm** to a person or persons. It is behaviour which obviously is likely to cause harm to another person or persons. All sexual assaults should be considered violent. Include criminal or civil sanctions i.e. all hospital admissions resulting from violence.

SOURCE	SUPPORTING INFORMATION
RATING	There is clear evidence that this risk factor is present There is sufficient evidence to suggest that this risk factor is partially present There is no evidence that this risk factor is present
RATING	This risk factor is clearly relevant to risk management This risk factor is partially relevant to risk management This risk factor is not relevant to risk management

H2. Young Age at First Violent Incident

Age categories: under 20; 20-39; 40+

SOURCE	SUPPORTING INFORMATION
RATING	There is clear evidence that this risk factor is present There is sufficient evidence to suggest that this risk factor is partially present There is no evidence that this risk factor is present
RATING	This risk factor is clearly relevant to risk management This risk factor is partially relevant to risk management This risk factor is not relevant to risk management

H3. Relationship instability

This item applies only to “romantic” intimate or non-platonic partnerships and excludes relationships with friends and family. Instability relates to many short-term relationships; absence of any relationships; presence of conflict within long-term relationships.

SOURCE	SUPPORTING INFORMATION
RATING	There is clear evidence that this risk factor is present There is sufficient evidence to suggest that this risk factor is partially present

	There is no evidence that this risk factor is present
RATING	This risk factor is clearly relevant to risk management This risk factor is partially relevant to risk management This risk factor is not relevant to risk management

H4. Employment problems

This relates to individuals who refuse to seek legitimate employment, or have a history of having many jobs within short-term periods, or frequently being fired or quitting employment

Note whether mental or physical disabilities were involved.

SOURCE	SUPPORTING INFORMATION
RATING	There is clear evidence that this risk factor is present There is sufficient evidence to suggest that this risk factor is partially present There is no evidence that this risk factor is present
RATING	This risk factor is clearly relevant to risk management This risk factor is partially relevant to risk management This risk factor is not relevant to risk management

H5. Substance use problems

Assessor is interested in whether there exists impairment of functioning in areas of health, employment, recreation, and interpersonal relationships, which is attributable to substances. Include neurological damage as a result of substance use. Include misuse of prescription drugs, as well as solvents and glue.

SOURCE	SUPPORTING INFORMATION
RATING	There is clear evidence that this risk factor is present There is sufficient evidence to suggest that this risk factor is partially present There is no evidence that this risk factor is present
RATING	This risk factor is clearly relevant to risk management This risk factor is partially relevant to risk management This risk factor is not relevant to risk management

H6. Major mental illness

This item is scored on the basis of past history and is unaffected by whether the disorder is currently active or in remission.

Include illnesses involving disturbances of thought and affect (e.g. psychotic illnesses, manic mood illnesses, organic illnesses, learning difficulties). Include even when diagnosis is unclear.

SOURCE	SUPPORTING INFORMATION
RATING	There is clear evidence that this risk factor is present There is sufficient evidence to suggest that this risk factor is partially present

	There is no evidence that this risk factor is present
RATING	This risk factor is clearly relevant to risk management This risk factor is partially relevant to risk management This risk factor is not relevant to risk management

H7. Psychopathy This item relates to the patients Psychopathy Checklist score	
SOURCE	SUPPORTING INFORMATION
RATING	There is clear evidence that this risk factor is present There is sufficient evidence to suggest that this risk factor is partially present There is no evidence that this risk factor is present
RATING	This risk factor is clearly relevant to risk management This risk factor is partially relevant to risk management This risk factor is not relevant to risk management

H8. Early Maladjustment This item taps maladjustment at home, school , or in the community before the age of 17. It includes two very different ways in which childhood maladjustment predicts later violence. One way is through childhood victimization, the other through the child being a childhood victimizer or delinquent.	
SOURCE	SUPPORTING INFORMATION
RATING	There is clear evidence that this risk factor is present There is sufficient evidence to suggest that this risk factor is partially present There is no evidence that this risk factor is present
RATING	This risk factor is clearly relevant to risk management This risk factor is partially relevant to risk management This risk factor is not relevant to risk management

H9. Personality Disorder This item relates to a diagnosis of a personality disorder which should conform to an official nosological system such as DSM or ICD. This item is scored on the basis of past history and is unaffected by whether the disorder is currently active or in remission	
SOURCE	SUPPORTING INFORMATION
RATING	There is clear evidence that this risk factor is present There is sufficient evidence to suggest that this risk factor is partially present There is no evidence that this risk factor is present
RATING	This risk factor is clearly relevant to risk management

	This risk factor is partially relevant to risk management This risk factor is not relevant to risk management
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H10. Prior Supervision Failure

This item is concerned with serious supervision failures while the individual was on parole, probation, or under the auspices of some correctional or mental health agency or institution.

Include minor failures resulting in minor disciplinary action such as returning late whilst on pass, causing a disturbance, failing to take medication as prescribed, using drugs or alcohol while prohibited.

SOURCE	SUPPORTING INFORMATION
RATING	There is clear evidence that this risk factor is present There is sufficient evidence to suggest that this risk factor is partially present There is no evidence that this risk factor is present
RATING	This risk factor is clearly relevant to risk management This risk factor is partially relevant to risk management This risk factor is not relevant to risk management

CLINICAL:

C1. Lack of Insight

This item refers to the degree to which the assessee fails to acknowledge and comprehend his or her mental disorder, and its effect on others.

SOURCE	SUPPORTING INFORMATION
RATING	There is clear evidence that this risk factor is present There is sufficient evidence to suggest that this risk factor is partially present There is no evidence that this risk factor is present
RATING	This risk factor is clearly relevant to risk management This risk factor is partially relevant to risk management This risk factor is not relevant to risk management

C2. Negative Attitudes

Here the authors are referring to the kind of pro-criminal or antisocial attitudes that have some likelihood of eventuating in violence. This does not refer to the occasional pessimistic or other such attitude, but to entrenched antisocial and negative attitudes and beliefs

SOURCE	SUPPORTING INFORMATION
RATING	There is clear evidence that this risk factor is present There is sufficient evidence to suggest that this risk factor is partially present

	There is no evidence that this risk factor is present
RATING	This risk factor is clearly relevant to risk management This risk factor is partially relevant to risk management This risk factor is not relevant to risk management

C3. Active Symptoms of Major Mental Illness

Clinicians in the course of examinations will be attentive to positive and negative psychotic symptoms – should follow a classification system

SOURCE	SUPPORTING INFORMATION
RATING	There is clear evidence that this risk factor is present There is sufficient evidence to suggest that this risk factor is partially present There is no evidence that this risk factor is present
RATING	This risk factor is clearly relevant to risk management This risk factor is partially relevant to risk management This risk factor is not relevant to risk management

C4. Impulsivity

Impulsivity refers to dramatic hour-to-hour, day-to-day, or week-to-week fluctuations in mood or general demeanour. It pertains to the inability to remain composed and directed even when under pressure to act. The Impulsivity Checklist (ICL-20) advanced by Webster and Jackson (1997b) has been recommended. Include overreactions to imagined slights and disappointments.

SOURCE	SUPPORTING INFORMATION
RATING	There is clear evidence that this risk factor is present There is sufficient evidence to suggest that this risk factor is partially present There is no evidence that this risk factor is present
RATING	This risk factor is clearly relevant to risk management This risk factor is partially relevant to risk management This risk factor is not relevant to risk management

C5. Unresponsive to Treatment

It is vital to know if the individual has sought help and accepted it, rejected it out of hand, or agreed to it merely to 'look good' to a court, review board or authority. May refuse treatment, start then stop, or "sham" their way through treatment but fail to benefit from it. Also include non-compliance with medication.

SOURCE	SUPPORTING INFORMATION
RATING	There is clear evidence that this risk factor is present There is sufficient evidence to suggest that this risk factor is partially present There is no evidence that this risk factor is present
RATING	This risk factor is clearly relevant to risk management

	This risk factor is partially relevant to risk management This risk factor is not relevant to risk management
--	--

RISK MANAGEMENT ITEMS:

R1. Plans Lack Feasibility This may be due to the fact that the community agencies are unwilling (due to patient's behaviour) or unable (due to lack of resources) to provide assistance. Alternatively the patient may have played no role in making plans or be uninvolved with peers or family. Finally, family and peers may be unwilling or unable to provide help. Include involvement with family during stay in The State Hospital. Include communications with social work.	
SOURCE	SUPPORTING INFORMATION
RATING	There is clear evidence that this risk factor is present There is sufficient evidence to suggest that this risk factor is partially present There is no evidence that this risk factor is present
RATING	This risk factor is clearly relevant to risk management This risk factor is partially relevant to risk management This risk factor is not relevant to risk management

R2. Exposure to Destabilisers This is meant to refer to situations in which persons are exposed to hazardous conditions to which they are vulnerable and which may trigger violent episodes. 'Hazardous conditions' are unique to individuals, but may include the presence of weapons, substances or some victim group. It is also related to lack of professional support or inadequate professional supervision .	
SOURCE	SUPPORTING INFORMATION
RATING	There is clear evidence that this risk factor is present There is sufficient evidence to suggest that this risk factor is partially present There is no evidence that this risk factor is present
RATING	This risk factor is clearly relevant to risk management This risk factor is partially relevant to risk management This risk factor is not relevant to risk management

R3. Lack of personal support It is important to determine exactly what services will be available from whom, and to look beyond the 'good intentions' of relatives and friends (and to ensure that such persons are, in fact, not simply being 'used' in an attempt to secure release or other privileges).	
SOURCE	SUPPORTING INFORMATION
RATING	There is clear evidence that this risk factor is present

	There is sufficient evidence to suggest that this risk factor is partially present There is no evidence that this risk factor is present
RATING	This risk factor is clearly relevant to risk management This risk factor is partially relevant to risk management This risk factor is not relevant to risk management

R4. Noncompliance with remediation attempts

This is coupled with motivation to succeed and willingness to comply with medication and other therapeutic regimes. Individuals who score high on this item may lack motivation to succeed and willingness to comply with medication and therapy, or refuse to follow rules. Should be constructed broadly to include remediation attempts in both therapeutic and supervision/management realms.

SOURCE	SUPPORTING INFORMATION
RATING	There is clear evidence that this risk factor is present There is sufficient evidence to suggest that this risk factor is partially present There is no evidence that this risk factor is present
RATING	This risk factor is clearly relevant to risk management This risk factor is partially relevant to risk management This risk factor is not relevant to risk management

R5. Stress

This part of the assessment entails trying to forecast what sources of stress the individual is likely to encounter, and how she or he may react to or cope with these. Suggested attention paid to three general areas: family, peer and employment

SOURCE	SUPPORTING INFORMATION
RATING	There is clear evidence that this risk factor is present There is sufficient evidence to suggest that this risk factor is partially present There is no evidence that this risk factor is present
RATING	This risk factor is clearly relevant to risk management This risk factor is partially relevant to risk management This risk factor is not relevant to risk management

Appendix 2.3 – PECC

THE STATE HOSPITAL

PECC (Shortened)

This shortened version of PECC should only be used in conjunction with other nursing assessment tools e.g BEST (Behavioural Status Index), LUNSERS etc.

RATING SCALE

The tool assesses the presence / absence of specific symptoms across 5 domains, positive symptoms, negative symptoms, depressive symptoms with associated suicidal ideation and insight into illness. There is a brief description of each domain attached to this document where each symptom is rated on a scale of 1-7 with the exception of suicidal ideation and insight which is rated on a 4 point rating scale. Please tick the rating that applies during the patient interview.

When trying to decide on a rating for these symptoms, consider whether each symptom has been present over the past week with the exception of suicidal ideation which is over the previous month. If present, how frequent, what level of distress / burden does it cause the patient and to what degree does it impact on their level of functioning? A summary rating is shown below with full rating scale attached to this document.

1-7 rating scale (1 = not present 7 = total disruption)

1	2	3	4	5	6	7
ABSENT	DOUBTFUL SUB- THRESHOLD MENTAL DISORDER	SYMPTOM PRESENT NOT FREQUENT LIMITED BURDON	SYMPTOM PRESENT +/-50 % SOME / CLEAR BURDON MODERATE / CLEAR IMPACT ON FUNCTIONING		PRESENT >50% PRONOUNCED / EXTREME BURDON SEVERE IMPACT ON FUNCTIONING	

The severity of a symptom is evaluated on the basis of three dimensions:

- * Frequency
- * Distress
- * Impact on level of functioning

In cases of doubt between two scores, the highest score is adopted.

Anchor Points PECC

- 1) Absent
- 2) Doubtful, sub-threshold mental disorder
- 3) Symptom is present but not frequently, limited burden
- 4) Frequent (-50%), some burden, moderate impact on functioning
- 5) Frequent (+50%), clear burden, clear impact on functioning
- 6) Frequent (+50%), pronounced burden, serious impact on functioning
- 7) Frequent (+50%), extreme burden all areas of functioning are disturbed, supervision necessary.

1	2	3	4	5	6	7
A certain pathology						
Significant impact on functioning						
Total disruption						

In case of doubt between two scores, the highest score is adopted.

For three of the symptoms (P2 grandiosity; D3 guilt feelings; D4 somatic concern) the general rule is that if the symptom has a psychotic dimension, even with a low frequency, the minimum score is 4.

Assessment definitions

Positive Symptoms

Delusions (P1)

Beliefs that are unfounded or unrealistic. The conviction is not such as is normally accepted by other members of the individuals cultural or sub-cultural group. Ranging from vague delusions which do not influence thought or behaviour to stable systematised delusions or multiple delusions which influence behaviour and impair functional capacity.

1	2	3	4	5	6	7

Grandiosity (P2)

Exaggerated self-evaluation or sense of self-worth; convictions of superiority or having a special extraordinary identity. The ideas can be of a religious, physical or other nature. Ranging from being boastful and feeling superior to others to considering oneself to have extraordinary abilities so that it influences one's behaviour and interplay with other people.

If the symptom has a psychotic dimension, even with a low frequency, the minimum score is 4.

1	2	3	4	5	6	7

Hallucinations (P3)

Visual, auditory, olfactory or somatic perceptions not generated by external stimuli. Ranging from isolated hallucinations to hallucinations with dominate the individuals thoughts and influence behaviour and functional capacity.

1	2	3	4	5	6	7

Unusual thought (P4)

Thinking characterised by strange, fantastic or bizarre ideas. Ranging from abnormal ideas to thinking dominated by absurd, grotesque or unusual ideas or delusions.

1	2	3	4	5	6	7

Negative Symptoms

Blunted affect (N2)

Subjective perception of emotional emptiness and inability to react emotionally, as described by the patient himself, or diminished emotional behaviour, as observed by others. Ranging from a degree of emotional sluggishness to a total lack of ability to experience emotions or react emotionally, which influences behaviour and impairs functional capacity.

1	2	3	4	5	6	7

Depressive symptoms

Depression (D2)

A subjective feeling of sadness, pessimism, dejection, a feeling of meaninglessness with suicidal thoughts. Ranging from mild dejection to profoundly depressed mood and feelings of hopelessness which influences behaviour and impairs functional capacity.

1	2	3	4	5	6	7

Guilt feelings (D3)

Sense of remorse for events or circumstances. Ranging from mild self-blame to a strong sense of guilt, which influences behaviour and impairs functional capacity.

1	2	3	4	5	6	7

Somatic concern (D4)

Concern about bodily functions, physical symptoms or somatic illness. Ranging from mild pre-occupation or diffuse malaise to delusional convictions of suffering from a serious physical disease.

1	2	3	4	5	6	7

Degree of suicidal intentions

The degree of suicidal intentions relates to the patient's thoughts and plans over the past month. The degree of suicidal intentions is rated on a scale of 1-4.

1. No suicidal ideation
2. Suicidal ideation without plans
3. Suicidal ideation with plans
4. Very frequent suicidal ideation with plans and/or suicide attempt.

Degree of Suicidal Ideation	None	Ideation without plans	Ideation with plans	Frequent ideation with plans / attempts
Degree (Please tick)				

Insight into illness

Symptoms: The ability to describe and recognise symptoms, e.g. hallucinations, delusions, blunted affect. Ranging from a clear perception of the symptoms to a total lack of understanding that various symptoms are really evidence of an illness.

Causes: The ability to see a causal relationship between symptoms and the mental illness the person is suffering from. Ranging from a very clear understanding of the fact that the symptoms one has are caused by mental illness to complete denial that one is suffering from mental illness.

Both are rated on a 4 point rating scale

1. Good insight
2. Majority of symptoms not all
3. Minority of symptoms
4. Completely absent

Insight into illness	Good	Majority of Symptoms	Minority of Symptoms	Absent
Symptom Insight (please tick)				
Causes insight (please tick)				

Appendix 2.4 – BEST Insight scale items

2. INSIGHT ASSESSMENT SUB-SCALE

PATIENT ID:		GENDER:		SERIAL NO:		WARD:	
AGE [ring as appropriate] :	1	2	3	4	5		
	< 25 yrs	25-35 yrs	36-45 yrs	46-55 yrs	> 55 yrs		
DSM-IV Diagnosis (es):							
RATER:				RATER'S ROLE [e.g., nurse; psychologist]			
DATE OF ASSESSMENT:							

[N.B: Please use only the stated criteria when completing this score sheet. Ring the appropriate number on the scale of 1 to 5 for each item]

1	Awareness of tension	1	2	3	4	5
2	Description of tension	1	2	3	4	5
3	Tension-reducing strategies	1	2	3	4	5
4	Recognition of negative or angry feelings	1	2	3	4	5
5	Tension-producing thoughts	1	2	3	4	5
6	Tension-producing events	1	2	3	4	5
7	Personal strategy for reducing tension	1	2	3	4	5
8	Identifying relaxing thoughts	1	2	3	4	5
9	Identifying relaxing activities	1	2	3	4	5
10	Attributes disliked in others	1	2	3	4	5
11	Attributes liked in others	1	2	3	4	5
12	Events producing insecurity	1	2	3	4	5
13	Events producing security	1	2	3	4	5
14	Antecedent events leading to treatment	1	2	3	4	5
15	Ascription of responsibility	1	2	3	4	5
16	Self-appraisal	1	2	3	4	5
17	Prioritisation of problems	1	2	3	4	5
18	Goal-planning	1	2	3	4	5
19	Compliance with therapy	1	2	3	4	5
20	Expectations	1	2	3	4	5

Appendix 2.5 – Original version of the UPSA

The UCSD Performance-based Skills Assessment Administration Manual Ver. 2.4 (UPSA-2-VIM)

Adapted for the MATRICS-CT
Validation of Intermediate Measures (VIM) Study
September, 2008

Thomas L. Patterson, Ph.D.
Brent T. Mausbach, Ph.D.

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Recent Change History:

Ver. 2.4, Rev. 11-03: Changed title to UPSA-2-VIM (previously UPSA-2); revised copyright notice
Ver. 2.3, Rev. 09-06: Major revision of Ver. 2.2 for the MATRICS-CT (a study of selected medication management, revised most tasks)

In the **Organization/Planning** domain, patients are asked to read a "newspaper article" describing the opening of a new Water Theme Park. Patients are then asked a few questions to evaluate their comprehension of the material and requested to list seven items they think are necessary to bring or wear in order to spend the whole day at the Water Park. Points are given for answers deemed appropriate, e.g., swimsuit, towel, sunscreen, jacket, umbrella, money, etc. This part of the assessment takes about five minutes to complete and yields scores ranging from 0 to 14.

The **Transportation** domain tests the use of public transportation. In the first part of this section patients are provided with bus schedules showing the routes for 3 different buses. Questions include which bus to ride to a specific destination, cost of the fare, finding the telephone number for trip planning and schedule information, where they would get off the bus to transfer to another bus and the location of two trolley stations identified on the map. The second part of this section requires the individual to use the information from a bus route schedule to answer questions about when to catch a bus in order to arrive in time for an appointment, length of waiting time for the arrival of the bus and destination arrival time. These last three questions are timed for one minute apiece. This task requires about five minutes to complete and yields scores ranging from 0 to 9.

In the **Household Management** domain, patients are provided with a recipe for rice dessert. They are then presented with an array of items that one might possibly have on hand in their pantry, e.g., pasta, jelly, cereal, soap, rice, canned tuna, mushrooms, canned vegetables, crackers, etc. Individuals are requested to read the recipe, check the pantry, and then prepare a list of the items missing from the pantry that they need to buy in order to make the rice dessert. Points are given for each correct item on the shopping list. This task is timed for five minutes and scores range from 0 to 4.

UCSD Performance-Based Skills Assessment (UPSA-2-VIM)

Description

The UCSD Performance-Based Skills Assessment (UPSA-2) is a role-play test designed to evaluate a person's functional capacity in five selected domains of basic living skills. These areas include Financial Skills, Communication, Organization/Planning, Transportation, and Household Management. Patients being tested utilize props to demonstrate how they perform everyday activities and are assessed on their actual performance.

This version of the UPSA-2 begins with the **Finance** domain, which tests the patient's ability to count money, make change and pay bills. In the first part of this task patients are provided with currency consisting of real coins (1 quarter, 4 dimes, 6 nickels, 8 pennies) (\$1.03 total) and reproductions of paper bills (3 one-dollar bills, 1 five-dollar bill, and 1 two-dollar bill). Patients are asked to count out given amounts of money (e.g., \$1.03, \$6.75, \$12.49), and also make change from two dollars. In the second part of the task patients are shown a bill from the Franklin Gas & Electric Company and asked questions to evaluate their understanding of the information included in the bill, e.g., who to pay, how much to pay, when to pay, etc. These tasks take about five minutes to complete and yield scores ranging from 0 to 11.

The next domain tested is **Communication**. Patients are provided with an unplugged telephone and asked to role-play a number of scenarios, e.g., what number to dial in case of an emergency, calling directory assistance to obtain a telephone number, and then dialing that number from memory. Patients are also requested to read a letter scheduling a medical appointment and then role-play calling the doctor's office to reschedule the appointment. In addition, patients are asked to describe how the letter requested them to prepare for the medical appointment (i.e., fast for a blood draw) and what two items they need to bring with them to the doctor (i.e., insurance coverage and list of medications). These tasks require about five minutes to complete and yield scores ranging from 0 to 12.

ADMINISTRATION & SCORING

- Instructions for each task may be given only once unless otherwise stated. Instructions may be repeated only when it is clear that the subject has not heard the instructions correctly or does not understand the test instructions.
- If a task is incorrectly performed, it is scored as incorrect. The tester should not provide a new trial for that task.
- A spontaneous incorrect response after a correct response is scored as incorrect.
- The tester should move from task to task throughout the test without giving the subject feedback about whether the responses are correct or incorrect.
- In this manual, all information written in standard text are instructions to the tester. Below the instructions are test boxes. Text in these boxes in **Bold Arial** type are prompts to be spoken to the subject, and text in **non-bold Arial** type are acceptable answers to questions and should not be read to the patient.

EQUIPMENT

- Role-play Cards:
 - ✓ Water Theme Park
 - ✓ Franklin Gas & Electric Bill
 - ✓ Medical Appointment Letter
 - ✓ Bus Maps for Buses: #12, #46, & #8
 - ✓ Rice Dessert Recipe
- Timer
- Currency
 - ✓ 1 two-dollar bill, 1 five-dollar bill, 3 one-dollar bills (play money)
 - ✓ 1 quarter, 4 dimes, 6 nickels, 8 pennies (real coins) (\$1.03 total change)
- Push-Button Telephone with large push-button pads on telephone base
- 39 Pantry Items & Placement Diagram
- Shopping List worksheet
- UPSA Scoring Form
- Optional: Magnifier glass (for patients with poor eyesight)

PROCEDURE

1. Introduce the testing by reading the following to the subject:

The tasks I'm now going to ask you to demonstrate include various kinds of everyday activities. I'll tell you what to do and then I would like you to show me how you would actually do these tasks using the props I'll give you.

1A. FINANCIAL SKILLS: COUNTING MONEY & MAKING CHANGE

Props

- ✓ 1 ten dollar bill *
- ✓ 3 one dollar bills *
- ✓ 1 five dollar bill *
- ✓ 1 quarter
- ✓ 4 dimes
- ✓ 6 nickels
- ✓ 5 pennies



Examiner/Tester

- * May substitute "play" money as long as it is a good facsimile of real money. Use only real coins.

Procedure

1. Lay out the paper currency in front of the subject from tester's left to right as shown above. The coins may be placed together in a group to the left of the \$5 bill. After the completion of each part of this task, the currency needs to be replaced in its original position.
2. Give the subject the following instructions: (If necessary, instructions may be repeated but not more than twice.)

Show me one dollar and two cents – all in coins.

NOTE TO TESTER: If the subject first counts out \$1.02 using a dollar bill, the tester should repeat the instructions to use ONLY coins. If the subject counts out \$1.02 again using the dollar bill, then the answer is scored as incorrect.

Additional prompts:	Correct answer:
Show me six dollars and seventy-three cents.	\$6.73
Show me twelve dollars and forty-nine cents.	\$12.49
Imagine that you are buying some items from a store. You give me, the cashier, ten dollars to pay the bill. (Tester takes ten-dollar bill from the currency laid out in front of subject). The items cost \$6.27. Show me how much change you should get back from \$10.00.	\$3.73

NOTE TO TESTER: The subject may NOT calculate how much change he/she should receive using pen and paper or a calculator.

Scoring & Timing

One point is given for each correct answer and 0 points for incorrect answers. This task yields scores ranging from 0 to 4 and should take about two minutes to complete.

1B. FINANCIAL SKILLS: PAYING BILLS

Props

- ✓ Role-play Card – Franklin Gas & Electric Company Bill

Procedure

1. Show the subject the bill from the Franklin Gas & Electric Company and say:

PROMPT:	Correct Answer:
Imagine that you received this bill from the utility company. What is the name of the company you need to pay?	Franklin Gas & Electric Company or FG&E
How much do you need to pay?	Eighty-four dollars and eighteen cents (\$84.18)
How much are the current charges?	Forty-four dollars and thirty-four cents (\$44.34)
Why is the new balance more than the current charges?	The bill for the previous month was not paid.
When do you need to pay this bill?	Before October 27
What is the service account number?	848792000
What telephone number can you call if you have questions about your bill?	1-800-411-FG&E or 1-800-411-3432

NOTE TO TESTER: Do not take away or conceal the utility bill. This is not a memory task. Give credit to any variation of the above answers if it is reasonable.

Scoring & Timing

One point is assigned for each correct item and 0 points for incorrect answers. This task yields scores ranging from 0 to 7 and should take about three minutes to complete.

2. COMMUNICATION SKILLS: TELEPHONE & LETTER

Props

- ✓ Role-play Card – Medical Doctor Appointment Letter
- Note: The date for the medical appointment should be at least one to two months ahead of the subject's testing date. The date in the letter will need to be changed regularly. Choose the first Monday of the month or the second Monday if the first falls on a holiday.
- ✓ Push-button telephone (disconnected). Make sure that the number keypad is located on the telephone base and NOT on the handset. Also, if possible, choose the model of telephone where the handset needs to be picked up in order to access the dialing pad.

Procedure

This task requires that the subject demonstrate that he/she knows how to use a telephone. This includes picking up the receiver, pushing the buttons for numbers, and speaking into the mouthpiece. The subject should put the receiver back and repeat this sequence for each task listed below. With the exception of dialing from memory, instructions are given only once.

1. Place the telephone in front of the subject and give the following instructions:

We're going to use this telephone for the next tasks. Even though it's disconnected, show me everything you normally do when using a telephone.	Answer: (dial) 9-1-1
First, show me what number you would dial for help in case of an emergency.	

2. Instruct the subject to do the following:

Please call directory assistance and ask for the telephone number of David Johnson who lives in Midtown.	Answer: (dial) 4-1-1 (speak) David Johnson, Midtown
--	---

(continues on next page)

3. Instruct the subject to do the following:

Listen carefully to this number and dial it from memory: 896-6996

NOTE TO TESTER: The number needs to be dialed from memory but may be repeated at the subject's request. If the subject starts dialing and then asks for the number, the examiner may present the whole number again. The subject can dial the remaining numbers in order or can hang up and dial the whole number. If the subject requests the examiner to repeat the number a third time, the examiner should tell the subject to dial whatever he/she remembers.

4. Instruct the subject to read the Medical Appointment letter by saying:

Imagine that this is a letter from your Doctor. Please read the letter out loud. Read it carefully because I will ask you some questions about it.

5. After the subject is finished reading, give the following instruction: (Do not remove or conceal the Medical Appointment letter from the subject.)

Call the doctor's office and leave a voice-mail message requesting to reschedule your medical appointment for the following day at the same time. Be sure to include all necessary information.

NOTE TO TESTER: The subject needs to find the telephone number for rescheduling appointments listed in the letter (555) 326-5612 and dial the number correctly (1 point); give his/her name (1 point); the date of the current appointment (SUNDAY, JUNE 6th [or month & date within a letter] at 8 a.m.) (1 point) and ask to reschedule the appointment for the following day at the same time (TUESDAY, JUNE 7th [or month & date following date within a letter] at 8 a.m.) (1 point), and leave a callback telephone number (1 point) (5 points total).

6. Remove or conceal the role-play card and ask the following:

What are the two items listed in the letter that you need to bring with you to the medical appointment?

Answers:

Medical insurance card
(Also accept: "Medicaid", etc.)
List of current medications (Also accept: "My medications")

7. Ask the following question:

What else did the letter ask you to do to prepare for the doctor's appointment?

Answer:

No food or liquids except water for 12 hours before the appointment

Scoring & Timing

One point is given for each correct answer and 0 points for incorrect answers. This task yields scores ranging from 0 to 12 and should take about five minutes to complete.

3. COMPREHENSION & PLANNING: WATER THEME PARK

Props

- ✓ Role-play Card: Newspaper article on "Opening of New Water Theme Park"
- ✓ Magnifier (if necessary)

Procedure

1. Show the subject the first role-play card (Water Theme Park) and give the following instructions:

Please read this article about the opening of a new Water Theme Park out loud. Read it carefully because I will ask you some questions about it.

2. When the subject finishes reading the story, remove or conceal the role-play card and ask the following questions:

PROMPT:	Answer:
According to the story you just read, what is the best way to get to the Water Park?	Shuttle
When does the Water Park open?	10 a.m.
When does the Water Park close?	8 p.m.
Tell me four activities you could do at the Water Park.	Acceptable answers: wave pool, inflatable boat, body slides, roller coaster, Ferris wheel, water wars, bumper car derby, go-kart races, eat at the SBO.
Imagine that you are going to the Water Park to spend the day. There might be many things you'd like to take with you but tell me SEVEN things you REALLY NEED to wear or bring with you in order to spend the whole day there?	Acceptable answers: bathing suit or swim trunks, sunscreen, towel, water, change of clothes, money, jacket or sweater, raincoat, umbrella, medications, etc. (One answer, at least, must reflect the fact that the day will turn cold and rainy.)

NOTE TO TESTER:

See Appendix A for further examples of appropriate and inappropriate answers for things to bring or wear to the Water Theme Park.

Scoring & Timing

One point is given for each correct answer and 0 points for incorrect answers. This task yields scores ranging from 0 to 14 and should take about five minutes to complete.

4. TRANSPORTATION: BUS SCHEDULES

Props

- ✓ Role-play Cards – Bus schedules for routes #22, #5, & #46

Procedure

- Place the three bus schedules side-by-side in front of the subject from tester's left to right (#22, #5, #46) and ask the following questions:

Looking at these bus schedules, tell me which bus you would take to go to the Grand International Airport.	Answer: Bus #22
--	--------------------

- Remove the bus schedule for #5 and #46 and ask the following questions pertaining to bus schedule #22 only:

PROMPT:	Answer:
How much is your bus fare for one ride?	\$2.00 for basic normal or \$1.00 for senior/disabled
What telephone number would you call for trip planning and other information?	(800) 242-3488
Look at the map for Route #22. Point to the two trolley stations.	Mulberry Lane & Grape Street
Point to the place where you would transfer to route 54.	Mango Boulevard & Larkspur Road

(continue on next page)

- Turn over bus schedule #22. Show the subject the schedule on the back and give the following instructions:

PROMPT:	Answer:
Look carefully at this schedule for bus #22. It shows the places where you can get on and off the bus and the times the bus will arrive at those places. Use this schedule to answer the next questions.	11 minutes
Imagine that you get off the Mulberry Lane trolley on Wednesday morning at 9:00 (PAUSE). You want to catch the bus to your house on Grand Avenue (PAUSE). How long will you wait before the bus arrives?	
What time will you get to Grand Avenue?	9:41 a.m.
Imagine that you have an appointment with your doctor at the Central Hospital for next Monday at 9:20 a.m. (PAUSE). You live on Grand Avenue next to the Grand Airport (PAUSE). What is the latest time you can catch the bus in order to arrive at the hospital in time for your appointment?	9:21 a.m.

NOTE TO TESTER:

The above three questions using the route schedule for bus #22 are timed. Allow the subject up to one minute to answer each question before proceeding to the next. The questions may be read twice if needed.

Scoring and Timing

For each of the above questions, one point is given for each correct answer and 0 point for incorrect answers. This task yields scores ranging from 0 to 3 and should take about five minutes to complete.

5. HOUSEHOLD MANAGEMENT: SHOPPING LIST

Props

- ✓ Role-play Card – Recipe for Rice Dessert
- ✓ Simulated Pantry (See Appendix B for list of grocery items). Set up the pantry items according to the diagram found in Appendix C. The items should be concealed from the subject's view, however possible, until the tester reveals the contents of the pantry for this task.
- ✓ Shopping List (attached to the back of the UPSA scoring sheet)
- ✓ Timer

Procedure

- Show the subject role-play card for the rice dessert recipe and instruct the subject as follows:

Our next task involves household skills. Look at this recipe for rice dessert. Here is the list of ingredients that you need to make the dessert. (Point to the list of ingredients.)

- Reveal the contents of the pantry to the subject. Give the shopping list and give to the subject and give the following instructions:

Imagine that this is your pantry at home. Look at the list of ingredients that you need for the recipe and check the pantry to see what items you already have and what items are missing. Please write down all the missing items on this shopping list so you can go to the store to buy them.	Answers: Sugar, Raisins, Cinnamon, Cloves
--	--

- Set the timer for five minutes and remove the shopping list when the timer rings.

NOTE TO TESTER: If the list contains more than five items, scoring is based on the FIRST FOUR ITEMS ONLY. One point is given for each correct answer and 0 point for incorrect answers. This task yields scores of 0 to 4. Since this is a timed task, it should take five minutes or less to complete.

- After the role-play has ended, if the subject asks about his/her performance, the tester should reassure the subject with some sort of positive comment, i.e.,

You listened carefully to the directions and tried very hard. Good job.

APPENDIX A

Scoring Examples for Water Theme Park Story

Bathing suit	1	Sun Pan	1
Sunscreen	1	Skate	1
Towel	1	Sandals/Flip-Flops	1
Swim hat	1	Raincoat	1
Swim umbrella	1	Jeans	1
Snacks	1	Sweater	1
Wine/Drinks	1	Run boots/boots	1
Change of clothes	1	Univels	1
Money	1	Shoes & socks	1
Tote bag/Backpack	1	Water goggles	1
Medications	1	Sunglasses	1
Beach ball/Frisbee	1	I.D.	1
Camera	1		
Ski boot	0		
Shower to cook lunch	0		
Beer	0		
Twinkies	0		
New outfit	0		
Myronians	0		
Baloney	0		
Life preserver rope	0		

These scores are a suggested rubric since each situation will be unique. In order to assign scores to answers, the examiner should rely on the following criteria:

1 = an item to bring or wear to the Water Theme Park which is really needed in order to spend the whole day there comfortably.

0 = an item which is illogical/unreasonable/unreasonable/illegal/etc.

Please consult with the authors in the event of specific scoring items and items that have not been addressed.

List of Pantry Items

1. Uncle Ben's Original Long-Grain White Rice	12 oz.
2. Mornie Tah	26 oz.
3. Dole Cracked Pineapple	8 oz.
4. Kellogg's Corn Flakes	12 oz.
5. Heinz Tomato Ketchup	20 oz.
6. Raipha Milk (or local brand)	1
7. Chicken of the Sea Chunk Light Tuna	6 oz.
8. Housebrand Cellulose Sponges	2 sponges
9. T.U.	1 item
10. Dai Monte Sweet Peas	8.5 oz. can
11. Kleenex Facial Tissues	1 pocket pack
12. Sugar Free Telle Gelatin	3 oz.
13. Dai Monte White Kernel Corn	8.75 oz. can
14. Concoction Elbow Macaroni	7 oz. box
15. Wobhouse Indian Dressing	8.5 oz. bottle
16. Egg Cartons	1 doz.
17. Hansen Honey Roasted Peanuts	32 oz. can
18. Keebler Chis Crackers	16 oz.
19. Starbuck's Concord Grape Jelly	32 oz.
20. Tropicana Original Orange Juice	64 oz.
21. Tide Laundry Detergent	40 oz. box
22. Campbell's Vegetable Soup	10.5 oz. can
23. Margarine (must say margarine, not vegetable oil spread)	16 oz. plastic tub
24. Ernie Sugar Free Hard Candy (unsweetened mint)	4 oz. pkg.
25. Caligato Toppings (regular flavor)	8.2 oz.
26. CocaCola	12.5 oz. can
27. Schilling German Hotdog	3.3 oz.
28. Pirella-Peterson Chaps	2.14 oz. bag
29. Schilling Pure Vanilla Extract	3.5 oz. bottle

Note: Since brands will differ in different regions of the country, it is permissible and actually preferable to use brands that are common to a particular area. Also, sizes may differ somewhat, and that is also permitted. However, each item must be present or something comparable.

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APPENDIX C

Diagram for Placement of Pantry Items

Back Row

Orange juice ♦ 7-Up ♦ Milk ♦ Blue Cracker ♦ Cereal ♦ Ketchup

Potato chips • Sponges • Salt • Salad Dressing • Jelly • Detergent

Peasants • Coca Cola • Soap • Corn • Candy • Eggs

Margarine • Jello • Penn • Kleenex

Teethpaste • Tuna • Nutmeg • Pineapple • Vanilla • Pears

Front Row

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11



FGEC

Franklin Gas & Electric Company

[illegible][illegible]

						Total Sales Charges	\$68.02
06/01/2018	06-27	06-27				2001.46%	220.07
07/01/2018	7-8	8-7					

Quantitative Reliability 214-4490
Reliability Image 274-1490 (B) & 214-4334
Non-Residence Change 121-4490 & 121-4470
Uninsured 121-4490

The **Top Water, Deep Dive** book details the **Meeting** components.

Electric Energy (kWh) (2003/2002 ratio)	12.89
Transportation	2.25
Construction	17.94
Waste Treatment Programs	0.22
Nuclear Decommissioning	58
Fixed Transfer Assets	6.00
Competition Transition Charge	28.26
Total Electric Costs	27.43

Group: info@wisc.edu
 David Miller, Rapid Reader, 6011

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Year (Energy Usage: MWh/yr)	2014 Actual	2014 Goal	Variance	2015 Goal	Variance
Thermal/Steam	0.9	0.7	0.2%	0.4	+0.2%
Water/Steam	0.8	0.8	+0.2%	0.1	-0.2%
Refined Fuel	25	25		25	

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Service Address: 7247 Maple St., Cleveland, OH 44122			
Service Address Window 6497816006	Due Month Sept 27	No. Notes Garden 27	Please Pay This Amount \$36.18

Make Payment To:
Franchise Gas & Electric Company (FGEC)
Georgetown, DE 41104-0001

Fluorescence spectra were recorded on a Shimadzu RF-10A fluorescence spectrophotometer.

	SCORE:	RESPONSE:
2. COMMUNICATION SKILLS:	Correct (1 point) Incorrect (0 points)	
Dial Emergency #:	_____	_____
Dial Directory Assistance:	_____	_____
Appropriate Inquiry:	_____	_____
Dial # from Memory:	_____	_____
	Correct (1 point) Incorrect (0 points)	
Dial # from Letter:	_____	_____
Patient name:	_____	_____
Date current appt:	_____	_____
Date rescheduled appt:	_____	_____
Return Telephone number:	_____	_____
Insurance Card:	_____	_____
Medication List:	_____	_____
Fast for Blood Draw:	_____	_____
3. COMPREHENSION/PLANNING:	Correct (1 point) Incorrect (0 points)	
Water Park Scenario:		
How to arrive:	_____	_____
Time open:	_____	_____
Time close:	_____	_____

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2

	SCORE:	RESPONSE:
	Correct (1 point) Incorrect (0 points)	
What to do:	_____	_____
	_____	_____
	_____	_____
Appropriate Items:	_____	_____
	_____	_____
	_____	_____
	_____	_____
4. TRANSPORTATION:	Correct (1 point) Incorrect (0 points)	
Bus to Grand Airport:	_____	_____
Bus Fare:	_____	_____
Bus Schedule Information:	_____	_____
Mulberry Lane Trolley Station:	_____	_____
Orange Street Trolley Station:	_____	_____

PATTERSON 2008 (5-09-08) - UPLA-2 (MATHICS-CT YDG)

3

	SCORE:	RESPONSE:
	Correct (1 point) Incorrect (0 points)	
Transfer to Bus #54:	_____	_____
Waiting time:	_____	_____
Time at destination:	_____	_____
Time to catch bus:	_____	_____
	SCORE:	RESPONSE:
5. HOUSEHOLD MANAGEMENT:	Correct (1 point) Incorrect (0 points)	
Super:	_____	_____
Raisins:	_____	_____
Cinnamon:	_____	_____
Cloves:	_____	_____

PATTERSON 2008 (5-09-08) - UPLA-2 (MATHICS-CT YDG)

4

SHOPPING LIST

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____

PATTERSON 2008 (5-09-08) - UPLA-2 (MATHICS-CT YDG)

5

UPSA-2.3 SUMMARY SCORING

Upon completion of the UPSA-2, scores are assigned for each of the five subtests. Points achieved for each subtest are summed and entered into the appropriate boxes in column 2 of the scoring worksheet. Subtest scores (column 6) are calculated using the formulas provided in columns 3, 4, and 5 of the worksheet. Fraction scores in column 6 are rounded to the nearest numeral, whereby a score of 3.1 would be rounded to 3, and 3.5 would be rounded to 4). An UPSA-2 Total Score (range = 0-100) is entered at the bottom of the worksheet by summing the subtest scores in column 6. See sample scoring worksheet calculations below. A blank UPSA-2 Summary Scoring Worksheet is provided on page 2.

UPSA-2 "Sample" Summary Scoring Worksheet

1	2	3	4	5	6
Domain	Total Score	+	Percent Correct	x 20	Subtest Score
Demands					
Financial	5	+ 11 =	45	x 20 =	9
Communication	4	+ 12 =	33	x 20 =	7
Comprehensive Planning	6	+ 14 =	43	x 20 =	9
Transportation	5	+ 8 =	56	x 20 =	11
Household Skills	5	+ 4 =	75	x 20 =	15
UPSA-2 Total Score (Range = 0-100)					51

UPSA-2.3 Summary Scoring Worksheet

1	2	3	4	5	6
Domain	Total Score	+	Percent Correct	x 20	Subtest Score
Demands					
Financial		+ 11 =		x 20 =	
Communication		+ 12 =		x 20 =	
Comprehensive Planning		+ 14 =		x 20 =	
Transportation		+ 8 =		x 20 =	
Household Skills		+ 4 =		x 20 =	
UPSA-2 Total Score (Range = 0-100)					

The UCSD Performance-based Skills Assessment Administration Manual

Ver. 2.4(b)

(UPSA-2-VIM)

Adapted for the MATRICS-CT
Validation of Intermediate Measures (VIM) Study
September, 2008

Thomas L. Patterson, Ph.D.
Brent T. Mausbach, Ph.D.

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Recent Change History:

Ver. 2.4aRev 12-08: Amended location specifics from USA to UK – State Hospital, Carstairs.

Ver. 2.4, Rev. 11-09: Changed title to UPSA-2-VIM (previously UPSA-2); revised copyright notice

Ver. 2.3, Rev. 09-08: Major revision of Ver 2.2 for the MATRICS-CT VIM study (deleted medicationmanagement, revised most tasks)

UCSD Performance-Based Skills Assessment

(UPSA-2-VIM)

Description

The UCSD Performance-Based Skills Assessment (UPSA-2) is a role-play test designed to evaluate a person's functional capacity in five selected domains of basic living skills. These areas include Financial Skills, Communication, Organisation/Planning, Transportation, and Household Management. Patients being tested utilise props to demonstrate how they perform everyday activities and are assessed on their actual performance.

This version of the UPSA-2 begins with the **Finance** domain, which tests the patient's ability to count money, give change and pay bills. In the first part of this task patients are provided with currency consisting of real coins (1 twenty pence, 4 ten pence pieces, 6 five pence pieces, 8 pennies) (£1.03 total) and reproductions of paper bills (3 one pound notes, 1 five-pound note, and 1 ten-pound note). Patients are asked to count out given amounts of money (e.g., £1.02, £6.73, £12.49), and also give change from ten pounds. In the second part of the task patients are shown a bill from Scottish Power and asked questions to evaluate their understanding of the information included in the bill, e.g., who to pay, how much to pay, when to pay, etc. These tasks take about five minutes to complete and yield scores ranging from 0 to 11.

The next domain tested is **Communication**. Patients are provided with an unplugged telephone and asked to role-play a number of scenarios, e.g., what number to dial in case of an emergency, calling directory enquiries to obtain a telephone number, and then dialling that number from memory. Patients are also requested to read a letter scheduling a medical appointment and then role-play calling the doctor's office to reschedule the appointment. In addition, patients are asked to describe how the letter requested them to prepare for the medical appointment (i.e., fast before giving a blood sample) and what two items they need to bring with them to the doctor (i.e., appointment letter and list of medications). These tasks require about five minutes to complete and yield scores ranging from 0 to 12.

In the **Organisation/Planning** domain, patients are asked to read a “newspaper article” describing the opening of a new Water Theme Park. Patients are then asked a few questions to evaluate their comprehension of the material and requested to list seven items they think are necessary to bring or wear in order to spend the whole day at the Water Park. Points are given for answers deemed appropriate, e.g., swimsuit, towel, sunscreen, jacket, umbrella, money, etc. This part of the assessment takes about five minutes to complete and yields scores ranging from 0 to 14.

The **Transportation** domain tests the use of public transportation. In the first part of this section patients are provided with bus timetable showing the routes for 3 different buses. Questions include which bus to ride to a specific destination, cost of the fare, finding the telephone number for trip planning and timetable information, where they would get off the bus to transfer to another bus and the location of two bus stops identified on the map. The second part of this section requires the individual to use the information from a bus route schedule to answer questions about when to catch a bus in order to arrive in time for an appointment, length of waiting time for the arrival of the bus and destination arrival time. These last three questions are timed for one minute apiece. This task requires about five minutes to complete and yields scores ranging from 0 to 9.

In the **Household Management** domain, patients are provided with a recipe for rice dessert. They are then presented with an array of items that one might possibly have on hand in their pantry, e.g., pasta, jelly, cereal, soup, rice, canned tuna, toothpaste, canned vegetables, crackers, etc. individuals are requested to read the recipe, check the pantry, and then prepare a list of the items missing from the pantry that they need to buy in order to make the rice dessert. Points are given for each correct item on the shopping list. This task is timed for five minutes and scores range from 0 to 4.

ADMINISTRATION & SCORING

1. Instructions for each task may be given only once unless otherwise stated. Instructions may be repeated only when it is clear that the subject has not heard the instructions correctly or does not understand the test instructions.
2. If a task is incorrectly performed, it is scored as incorrect. The tester should not provide a new trial for that task.
3. A spontaneous incorrect response after a correct response is scored as incorrect.
4. The tester should move from task to task throughout the test without giving the subject feedback about whether the responses are correct or incorrect.
5. In this manual, all information written in standard text are instructions to the tester. Below the instructions are text boxes. Text in these boxes in **bold Arial type** are prompts to be spoken to the subject, and text in non-bold Arial type are acceptable answers to questions and should not be read to the patients.

EQUIPMENT

1. Role-play Cards:
 - ✓ Water Theme Park
 - ✓ Scottish Power Gas & Electric Bill
 - ✓ Medical Appointment Letter
 - ✓ Route Maps for Buses:
#22, #46, & #8
 - ✓ Rice Dessert Recipe
2. Timer
3. Currency
 - 1 ten-pound note, 1 five-pound note, 3 one-pound coins (play money)
 - 1 twenty pence piece, 4 ten pence pieces, 7 five pence pieces, 8 pennies (real coins) (£1.03 total change)
4. Push-Button Telephone with large push-button pads on telephone base
5. 29 Pantry Items & Placement Diagram
6. Shopping List worksheet
7. UPSA Scoring Form
8. Optional: Magnifying glass (for patients with poor eyesight)

PROCEDURE

1. Introduce the testing by reading the following to the subject:

The tasks I'm now going to ask you to demonstrate include various kinds of everyday activities. I'll tell you what to do and then I would like you to show me how you would actually do these tasks using the props I'll give you.

1A. FINANCIAL SKILLS: COUNTING MONEY & GIVING CHANGE

Props

- ✓ 1 ten pound note *
- ✓ 3 one pound coins *
- ✓ 1 five pound note *
- ✓ 1 twenty pence piece
- ✓ 4 ten pence pieces
- ✓ 7 five pence pieces
- ✓ 8 pennies

* May substitute “play” money as long as it is a good facsimile of real money.

Use only real coins.

Procedure

1. Lay out the paper currency in front of the subject from tester's left to right as shown above. The coins may be placed together in a group to the left of the £5 note. After the completion of each part of this task, the currency needs to be replaced in its original position.

2. Give the subject the following instructions: (If necessary, instructions may be repeated but not more than twice).

Show me one pound and two pence – all in coins. Do not use the £1 coin.

NOTE TO TESTER: If the subject first counts out £1.02 using a pound coin, the tester should repeat the instruction to use ONLY coins below the value of £1. If the subject counts out £1.02 again using the pound coin, then the answer is scored as incorrect.

<i>Additional prompts:</i>	<i>Correct answer:</i>
Show me six pounds and seventy-three pence.	£6.73
Show me twelve pounds and forty-nine pence.	£12.49
Imagine that you are buying some items from a store. You give me, the cashier, ten pounds to pay the bill. (Tester takes ten-pound bill from the currency laid out in front of subject). The items cost £6.27. Show me how much change you should get back from £10.00.	£3.73

NOTE TO TESTER: The subject may NOT calculate how much change he/she should receive using pen and paper or a calculator.

Scoring & Timing

One point is given for each correct answer and 0 points for incorrect answers.

This task yields scores ranging from 0 to 4 and should take about two minutes to complete.

1B. FINANCIAL SKILLS: PAYING BILLS

Props

✓ Role-play Card – Scottish Power Gas & Electricity Bill

Procedure

1. Show the subject the bill from Scottish Power and say:

PROMPT:	Correct Answer:
Imagine that you received this bill from the utility company. What is the name of the company you need to pay?	Scottish Power
How much do you need to pay?	Eighty-four pounds and eighteen pence (£84.18)
How much are the current charges?	Forty-four pounds and thirty-four cents (£44.34)
Why is the new balance more than the current charges?	The bill for the previous month was not paid.
When do you need to pay this bill?	Before 27 th October
What is the account number?	8497936006
What telephone number can you call if you have questions about your bill?	0845 2700 700 or 0845 027 4500

NOTE TO TESTER: Do not take away or conceal the utility bill. This is not a memory task. Give credit to any variation of the above answers if it is reasonable.

Scoring & Timing

One point is assigned for each correct item and 0 points for incorrect answers. This task yields scores ranging from 0 to 7 and should take about three minutes to complete.

2. COMMUNICATION SKILLS: TELEPHONE & LETTER

Props

✓ **Role-play Card** - Medical Doctor Appointment Letter

Note: The date for the medical appointment should be at least one to two months ahead of the subject's testing date. The date in the letter will need to be changed regularly. Choose the first Monday of the month or the second Monday if the first falls on a holiday.

✓ **Push-button telephone** (disconnected). Make sure that the number keypad is located on the telephone base and NOT on the handset. Also, if possible, choose the model of telephone where the handset needs to be picked up in order to access the dialing pads.

Procedure

This task requires that the subject demonstrate that he/she knows how to use a telephone. This includes picking up the receiver, pushing the buttons for numbers, and speaking into the mouthpiece. The subject should put the receiver back and repeat this sequence for each task listed below. With the exception of dialing from memory, instructions are given only once.

1. Place the telephone in front of the subject and give the following instructions:

We're going to use this telephone for the next tasks. Even though it's disconnected, show me everything you normally do when using a telephone. First, show me what number you would dial for help in case of an emergency.	Answer: (dial) 999
--	--------------------

2. Instruct the subject to do the following:

Please call directory enquiries and ask for the telephone number of David Johnson who lives in Motherwell.	Answer: (dial) 118 (speak) David Johnson, Motherwell
---	---

3. Instruct the subject to do the following:

Listen carefully to this number and dial it from memory: 596-6996
--

NOTE TO TESTER: The number needs to be dialed from memory but may be repeated at the subject's request. If the subject starts dialing and then asks for the number, the

examiner may present the whole number again. The subject can dial the remaining numbers in order or can hang up and dial the whole number. If the subject requests the examiner to repeat the number a third time, the examiner should tell the subject to dial whatever he/she remembers.
(continues on next page)

4. Instruct the subject to read the Medical Appointment letter by saying:

Imagine that this is a letter from your Doctor. Please read the letter out loud. Read it carefully because I will ask you some questions about it.

5. After the subject is finished reading, give the following instructions: (Do not remove or conceal the Medical Appointment letter from the subject).

Call the doctor's office and leave a voice-mail message requesting to reschedule your medical appointment for the following day at the same time. Be sure to include all necessary information.

NOTE TO TESTER: The subject needs to find the telephone number for rescheduling appointments listed in the letter (0141) 324-5612 and dial the number correctly (1 point), give his/her name (1 point), the date of the current appointment (MONDAY 1st OCTOBER [or month & date written in letter] at 8 a.m.) (1 point) and ask to reschedule the appointment for the following day at the same time (TUESDAY 2nd OCTOBER [or month & date following date written in letter] at 8 a.m.) (1point), and leave a callback telephone number (1 point) (5 points total).

6. Remove or conceal the role-play card and ask the following:

What are the two items listed in the letter that you need to bring with you to the medical appointment?

Answers:
This appointment letter
List of current medications (Also accept: "My medications")

7. Ask the following question:

What else did the letter ask you to do to prepare for the doctor's appointment?

Answer:
No food or liquids except water for 12 hours before the appointment

--	--

Scoring & Timing

One point is given for each correct answer and 0 points for incorrect answers. This task yields scores ranging from 0 to 12 and should take about five minutes to complete.

3. COMPREHENSION & PLANNING: WATER THEME PARK

Props

✓ Role-play Card: Newspaper article on “Opening of New Water Theme Park”

✓ Magnifier (if necessary)

Procedure

1. Show the subject the first role-play card (Water Theme Park) and give the following instructions:

Please read this article about the opening of a new Water Theme Park out loud. Read it carefully because I will ask you some questions about it.

2. When the subject finishes reading the story, remove or conceal the role-play card and ask the following questions:

PROMPT:	Answer:
According to the story you just read, what is the best way to get to the Water Park?	Shuttle
When does the Water Park open?	10 a.m.
When does the Water Park close?	9 p.m.
Tell me four activities you could do at the Water Park.	Acceptable answers: wave pool, inflatable boat, body slides, roller coaster, Ferris wheel, water wars, bumper car derby, go-kart races, eat at the BBQ
Imagine that you are going to the Water Park to spend the day. There might be many things you'd like to take with you but tell me <u>SEVEN</u> things you <u>REALLY NEED</u> to wear or bring with you in order to spend the whole day there?	Acceptable answers: bathing suit or swim trunks, sunscreen, towel, water/drinks, change of clothes, money, jacket or sweater, raincoat, umbrella, medications, Camera, Beach ball/Fins, Tote bag/Backpack, Snacks, Bus Pass, I.D, Water goggles, Shoes & socks, Rain boots/boots, Shorts, Sandals/Flip-Flops, Sunglasses Sun hat (One answer, at least, must reflect the fact that the day will turn cold and rainy).

NOTE TO TESTER:

See Appendix A for further examples of appropriate and inappropriate answers for things to bring or wear to the Water Theme Park.

Scoring & Timing

One point is given for each correct answer and 0 points for incorrect answers. This task yields scores ranging from 0 to 14 and should take about five minutes to

complete.

4. TRANSPORTATION: BUS TIMETABLES

Props

√Role-play Cards: – Bus timetables for routes #22, #8, & #46

√Stopwatch

Procedure

1. Place the three bus timetables side-by-side in front of the subject from tester's left to right (#22, #8, #46) and ask the following questions:

Looking at these bus schedules, tell me which bus you would take to go to the Grand International Airport.	Answer: Bus #22
---	---------------------------

2. Remove the bus schedules for #8 and #46 and ask the following questions pertaining to bus schedule #22 only.

PROMPT:	Answer:
How much is your bus fare for one journey?	£2.00 for basic normal or £1.00 for senior citizen/disabled
What telephone number would you call for trip planning and other information?	(0141) 242-3456
Look at the map for Route #22. Point to the two bus stations.	Mulberry Lane & Grape Street
Point to the place where you would transfer to route 54.	Mango Boulevard & Larkspur Road

3. Turn over bus schedule #22. Show the subject the schedule on the back and give the following instructions:

PROMPT:	Answer:
Look carefully at this schedule for bus #22. It shows the places where you can get on and off the bus and the times the bus will arrive at those places. Use this schedule to answer the next questions. Imagine that you get off the Mulberry Lane Bus station on Wednesday morning at 9:00 (PAUSE). You want to catch the bus to your house on Grand Avenue	11 minutes

(PAUSE). How long will you wait before the bus arrives?	
What time will you get to Grand Avenue?	9:41 a.m.
<p>(continues over page)</p> <p>Imagine that you have an appointment with your doctor at the Central Hospital for next Monday at 9:20 a.m. (PAUSE). You live on Grand Avenue next to the Grand Airport (PAUSE). What is the latest time you can catch the bus in order to arrive at the hospital in time for your appointment?</p>	8:21 a.m.

NOTE TO TESTER:

The above three questions using the route schedule for bus #22 are timed.

Allow the subject up to one minute to answer each question before proceeding to the next. The questions may be read twice if needed.

Scoring and Timing

For each of the above questions, one point is given for each correct answer and 0 points for incorrect answers. This task yields scores ranging from 0 to 9 and should take about five minutes to complete.

5. HOUSEHOLD MANAGEMENT: SHOPPING LIST

Props

✓ **Role-play Card:** – Recipe for Rice Dessert

✓ **Simulated Pantry** (See Appendix B for list of grocery items). Set up the pantry items according to the diagram found in Appendix C. The items should be concealed from the subject's view, however possible, until the tester reveals the contents of the pantry for this task.

✓ **Shopping List** (attached to the back of the UPSA scoring sheet)

✓ **Timer**

Procedure

1. Show the subject role-play card for the rice dessert recipe and instruct the subject as follows:

Our next task involves household skills. Look at this recipe for rice dessert. Here is the list of ingredients that you need to make the dessert.
(Point to the list of ingredients).

2. Reveal the contents of the pantry to the subject. Give the shopping list and pen to the subject and give the following instructions:

Imagine that this is your pantry at home. Look at the list of ingredients that you need for the recipe and check the pantry to see what items you already have and what items are missing. Please write down all the missing items on this shopping list so you can go to the store to buy them.

Answers:
Sugar, Raisins, Cinnamon, Cloves

3. Set the timer for five minutes and remove the shopping list when the timer rings.

NOTE TO TESTER: If the list contains more than four items, scoring is based on the

FIRST FOUR ITEMS ONLY. One point is given for each correct answer and 0 points for incorrect answers. This task yields scores of 0 to 4. Since this is a timed task, it should take five minutes or less to complete.

4. After the role-play has ended, if the subject asks about his/her performance, the tester should reassure the subject with some sort of positive comment, i.e.,

You listened carefully to the directions and tried very hard. Good job.

APPENDIX A

Scoring Examples for Water Theme Park Story

Bathing suit	1	Bus Pass	1
Sunscreen	1	Shorts	1
Towel	1	Sandals/Flip-Flops	1
Sun hat	1	Raincoat	1
Sun umbrella	1	Jacket	1
Snacks	1	Sweater	1
Water/Drinks	1	Rain boots/boots	1
Change of clothes	1	Umbrella	1
Money	1	Shoes & socks	1
Tote bag/Backpack	1	Water goggles	1
Medications	1	Sunglasses	1
Beach ball/Fins	1	I.D.	1
Camera	1		
Ski boat	0		
Stove to cook lunch	0		
Beer	0		
Twinkies	0		
New outfit	0		
Mayonnaise	0		
Baloney	0		
Life preserver rope	0		

These scores are a suggested rubric since each situation will be unique. In order to assign scores to answers, the examiner should rely on the following criteria:

1 = an item to bring or wear to the Water Theme Park which is really needed in order to spend the whole day there comfortably.

0 = an item which is illogical/unacceptable/unreasonable/illegal/etc.

Please consult with the authors in the event of specific scoring items and issues that have not been addressed.

APPENDIX B

UPSA PANTRY ITEMS – CHECKLIST

No	Items
1	Uncle Ben's Long Grain Rice
2	SAXA fine sea salt
3	Tesco pineapple pieces
4	Kellogg's Corn Flakes
5	Heinz Tomato ketchup
6	Tesco milk
7	Princes Tuna Steak
8	Sponges
9	7-up (2 litres)
10	Bachelor's dried peas
11	Kleenex tissues
12	Hartley's strawberry jelly
13	ASDA mini corn cobs
14	Marshall's macaroni
15	Hellman's French dressing
16	Egg carton
17	KP honey roast peanuts
18	Rakusen's Crackers
19	Hartley's strawberry jam
20	Tesco Orange Juice
21	Laundry detergent
22	Bachelor's Cup-a-Soup
23	Flora margarine
24	Tesco mint humbugs
25	Colgate toothpaste
26	Coca Cola (500ml)
27	Nutmeg
28	Walker's Ready Salted
29	Silver spoon vanilla extract

APPENDIX C

Diagram for Placement of Pantry Items

Back Row

Orange juice ◇ 7-Up ◇ Milk ◇ Crackers ◇ Cereal ◇ Ketchup

Crisps ◇ Sponges ◇ Salt ◇ Salad Dressing ◇ Jelly ◇ Detergent

Peanuts ◇ Coca Cola ◇ Soup ◇ Corn ◇ Mint sweets ◇ Eggs

Margarine ◇ Jam ◇ Peas ◇ Kleenex

Toothpaste ◇ Tuna ◇ Nutmeg ◇ Pineapple ◇ Vanilla ◇ Pasta

Front Row



Previous Balance £39.84	Payments Received £0.00	Current Charges £44.34	New Balance £84.18
--	--	---	-------------------------------------

Service Rate Meter#	Dates/Meter Readings	Meter Constant	Therm Multiplier	Total Usage	Amount
GAS/GR #00853677	21-08 23-09 582 602	1.000	1.009	20 Therms	£16.92

Baseline Allowance 18 Therms
 Baseline 18 Therms @ £.62672 16/33 Days
 Non-Baseline 2 Therms @ £.83920 16/33 Days
 Baseline 18 Therms @ £.65271 17/33 Days
 -Baseline 2 Therms @ £.86519 17/33 Days
 SDG&E's Average Cost Per Therm This month £20642
 Total Gas Charges £16.92

ELEC/DR #01512908	21-08 23-09 7989 8278	1	289 kWh	£30.47
----------------------	--------------------------	---	---------	--------

Baseline Allowance 274 kWh
 Baseline Usage 274 kWh @ £.10438
 Non-Baseline Usage 15 kWh @ £.12470
 Legislated 10% Reduction -3.05
Total Electricity Charges £27.42

The Total Electricity Charges shown above include the following components.
 Please see definitions on back of bill.

Electric Energy (£.042837/kWh).....	12.38
Transmission	2.33
Distribution	12.64
Public Purpose Programs	1.13
Nuclear Decommissioning.....	.58
Trust Transfer Amount 4.60
Competition Transition Charge	-6.24
Total Electricity Costs.....	27.42

Email: Info@scottishpower.com Questions? Please Call: 0845 2700 700 or 0845 027 4500
 Next Meter Reading Date: 22-10

Your Energy Usage History:	This Month Therms/day 0.6 KWh/day 8.8 Billing Days 33	Last Month Percent Change 0.7 -7.5% 8.5 +3.2% 29	This Month Percentage Last Year 0.4 11.2 33	Change +42.9% -21.5%
-------------------------------	--	--	--	----------------------------

 Please return this portion with your payment.
 Service Address: 2249 Maple St., Glasgow, G1 3PR

Service Account Number 8497936006	Date Mailed Sept 27	Pay Before October 27	Please Pay This Amount £84.18
--------------------------------------	------------------------	--------------------------	--

Make Payment To:

Scottish Power plc PO Box 1839, Glasgow, G9 8XB Please write your account number on your cheque.



MOTHERWELL CENTRAL MEDICAL
GROUP
101 FIRST AVE.
MOTHERWELL, ML11AZ

Dear Patient:

This letter is to remind you of your upcoming annual check up. Your appointment with:

DR. JAMES HUTCHIN
MOTHERWELL CENTRAL MEDICAL GROUP
101 FIRST AVE
MOTHERWELL

has been scheduled for:

MONDAY 1st October 2012 8 A.M.

Please note:

**YOU ARE SCHEDULED TO GIVE A BLOOD SAMPLE AT THIS APPOINTMENT.
DO NOT EAT ANY FOOD OR DRINK LIQUIDS EXCEPT WATER FOR THE
12-HOUR PERIOD BEFORE YOUR APPOINTMENT.**

PLEASE REMEMBER TO BRING WITH YOU THE FOLLOWING:

- 1) THIS APPOINTMENT LETTER
- 2) LIST OF CURRENT MEDICATIONS

TO RESCHEDULE, OR FOR ANY QUESTIONS REGARDING YOUR
APPOINTMENT, PLEASE CALL (0141) 324-5612.

Thank you,

JAMES HUTCHIN, M.R.C.G.P.
GENERAL PRACTITIONER



When you picked up the local newspaper this morning, this front-page headline struck your eye:

GRAND OPENING OF NEW WATER PARK!

Wild Water is the country's newest and largest water theme park with over 40 acres of water thrills for all ages. Come and surf the waves in the heated million-gallon wave pool. Then float down the "Rio River" in an inflatable boat. Thrill-seekers may try the heart-pounding twists and turns in the 5-story body slides and plunge down 200 feet on the water flume rides. For the land lubbers, there's the thrilling all-wooden roller coaster and the largest Ferris Wheel in the country.

To celebrate the Grand Opening, free special events will take place. Family Fun Day begins at 10 a.m. with a number of fun events including Water Wars, Bumper Car Water Derby, and Go-karting Races. Many great prizes will be awarded. Included in the admission price is a delicious barbecue featuring hot dogs, chips, Ice creams, and soft drinks.

Wild Water Theme Park is open 7 days a week from 10 a.m. to 9 p.m. Admission to the Family Fun Day is £5.00 (£3.00 Disabled) including all events and food. Since there is no bus service to the Park and parking is expensive, we recommend taking the free shuttle service. Shuttles run from midtown to the park every 15 minutes. For more information call (0141) 815-3958.

The Grand Opening is tomorrow and you want to spend the whole day at the Water Park. The weather report predicts a hot sunny day with a high temperature of 95 degrees. However, at sundown the temperature will drop quickly to a cool and windy 55 degrees with an 80% chance of rain. You decide to spend the whole day, from opening until closing, at the Water Park.



RICE DESSERT

Serves 4



- 1 1/2 cups Uncle Ben's converted white rice**
- 1 cup milk**
- 2 eggs**
- 2 tablespoons margarine**
- 1/3 cup sugar, or more or less to taste**
- 3/4 cup raisins**
- 2 teaspoons vanilla extract**
- 1 teaspoon cinnamon**
- 1/4 teaspoon each ground nutmeg and ground cloves**

Cook the rice as directed on the package. When it is done, pre-heat the oven to 325 degrees F.

Combine the cooked rice in a mixing bowl with the remaining ingredients. Mix thoroughly and pour the mixture into an oiled large shallow baking dish. Cover with a lid or foil and bake for 30 minutes. Then uncover and bake for 10 minutes longer.



ID# _____ STUDY _____ DATE _____
 INT _____

UCSD PERFORMANCE-BASED SKILLS ASSESSMENT SCORING FORM (UPSA-2)

SCORE:

RESPONSE:

1A. FINANCIAL SKILLS:
 Counting and Giving Change

Correct (1 point)
 Incorrect (0 points)

£1.02 (in coins)

£6.73

£12.49

Change from £10.00

1B. FINANCIAL SKILLS:
 Paying Bills

Correct (1 point)
 Incorrect (0 points)

Company: _____

Payment due: _____

Current charges: _____

New balance: _____

Due date: _____

Account number: _____

Telephone number: _____

SCORE: RESPONSE:

2. COMMUNICATION SKILLS:
Incorrect (0 points)

Correct (1 point)

Dial Emergency #: _____

Dial Directory Assistance: _____

Appropriate Inquiry: _____

Dial # from Memory: _____

Correct (1 point)
Incorrect (0 points)

Dial # from Letter: _____

Patient name: _____

Date current appt: _____

Suggested appointment date _____

Return Telephone number: _____

Appointment letter: _____

Medication List: _____

Fast for Giving Blood Sample: _____

3. COMPREHENSION/PLANNING: Correct (1 point)
Incorrect (0 points)
Water Park Scenario

How to arrive: _____

Time open: _____

Time close: _____

SCORE:RESPONSE:

Correct (1 point)

Incorrect (0 points)

What to do:

Appropriate Items:

4. TRANSPORTATION: Correct (1 point)
Incorrect (0 points)

Bus to Grand Airport: _____

Bus Fare: _____

Bus Schedule Information: _____

Bus Station#1: _____

Bus Station#2: _____

SCORE:

Correct (1 point)

Incorrect (0 points)

Transfer to Bus #54:

RESPONSE:

Waiting time:

Time at destination:

Time to catch bus:

SCORE: RESPONSE:

5. HOUSEHOLD MANAGEMENT: Correct (1 point)
Incorrect (0 points)

Sugar _____

Raisins _____

Cinnamon _____

Cloves _____

SHOPPING LIST

1. _____

2. _____

3. _____

4. _____

5. _____

6. _____

7. _____

8. _____

ROUTE 22

FARE INFORMATION

Fares and Schedules Subject to Change

FARES – Exact fare, please

Basic £2.00

Senior Citizen/Disabled £1.00

Children 5 and Under Free

PREPAID FARES

Token Pack

(11 tokens for the price of ten)

Tokens are good for fare only on buses

Monthly Ready Pass £54.00

Senior Citizen/Disabled £13.50

Youths (18 and under) £26.00

(ID may be requested)

@ Discounted passes made possible by Transnet

- When transferring to a route with a higher cash fare of monthly pass then originally paid, an upgrade for the difference is required. Upgrades may be paid on the original or connecting vehicle. Senior Citizen/Disabled passengers pay no upgrades.

Take advantage of Two Special Offers for Friends and Family!

Family Weekends – Two children (12 years old and under) travel for free with all adult (18+) fare paying passengers every weekend.

Friends travel for free on selected holidays when one person pays by cash, ticket or token or uses a Ready Pass, a friend gets the same full journey free. Look out for Friends Travel for Free on New Years Day, Public Holidays and Christmas.

INFORMATION: for trip planning and other information 0141-242-3456; (TTY/TDD for hearing impaired, 0141-323-7890); InfoExpress, 24-hour departure information via touch time phone, 0141-798-3223. MTS Online: www.buscommute.com.

REGIONAL TRANSFER POLICY

A transfer slip is issued only when fare is paid. It is good until the date and time shown (App. 90 minutes from the last time point). Round trips may be made during this time. A transfer may be used to connect to any regular MTS bus, tram, coach and train connection. Upgrades may be required.

SENIOR CITIZEN/DISABLED PASSENGERS: must show proof of eligibility (driving licence, DVLA Senior Citizen/Disabled card, pension or concessions cards upon request.

FAREBOXES: accept £1 notes, coins but do not give change.

PRIORITY SEATING: at the request of the driver, please reserve the seats at the front of the bus for Senior citizens and the Disabled.

ANIMALS: Trained guide dogs may accompany persons with disabilities. Other animals must be in an enclosed carrier and transported without assistance by the driver or operator. The carrier must be placed on the passenger's lap or under a seat.

THE TRANSIT STORE: 102 Broadway at 1st street, 234-1060 (weekdays 8:30AM-5:30PM, weekends Noon- 4:00PM). Passes, tickets, tokens, schedules, lost & found, ID cards 9weekdays 9:00AM-4:30Pm, weekends Noon to 3:00PM). Closed Holidays.

HOW TO USE THE BIKE BUS

When preparing to board a bike bus, make certain the driver knows you want to place your bike in the rack which is located at the front of the bus. Place both wheels of the bike in an upright position in the rack provided. Secure your bike in place. There is no charge for use of the bike rack. When removing your bike from the bike rack, again, make certain the driver knows you wish to remove your bike. Metropolitan Transit does not assume any responsibility for improper loading or use of the bike rack.

The schedules and other arrangements shown in the timetable are subject to change. Metropolitan Transit does not assume responsibility for errors in timetables, nor for any inconvenience

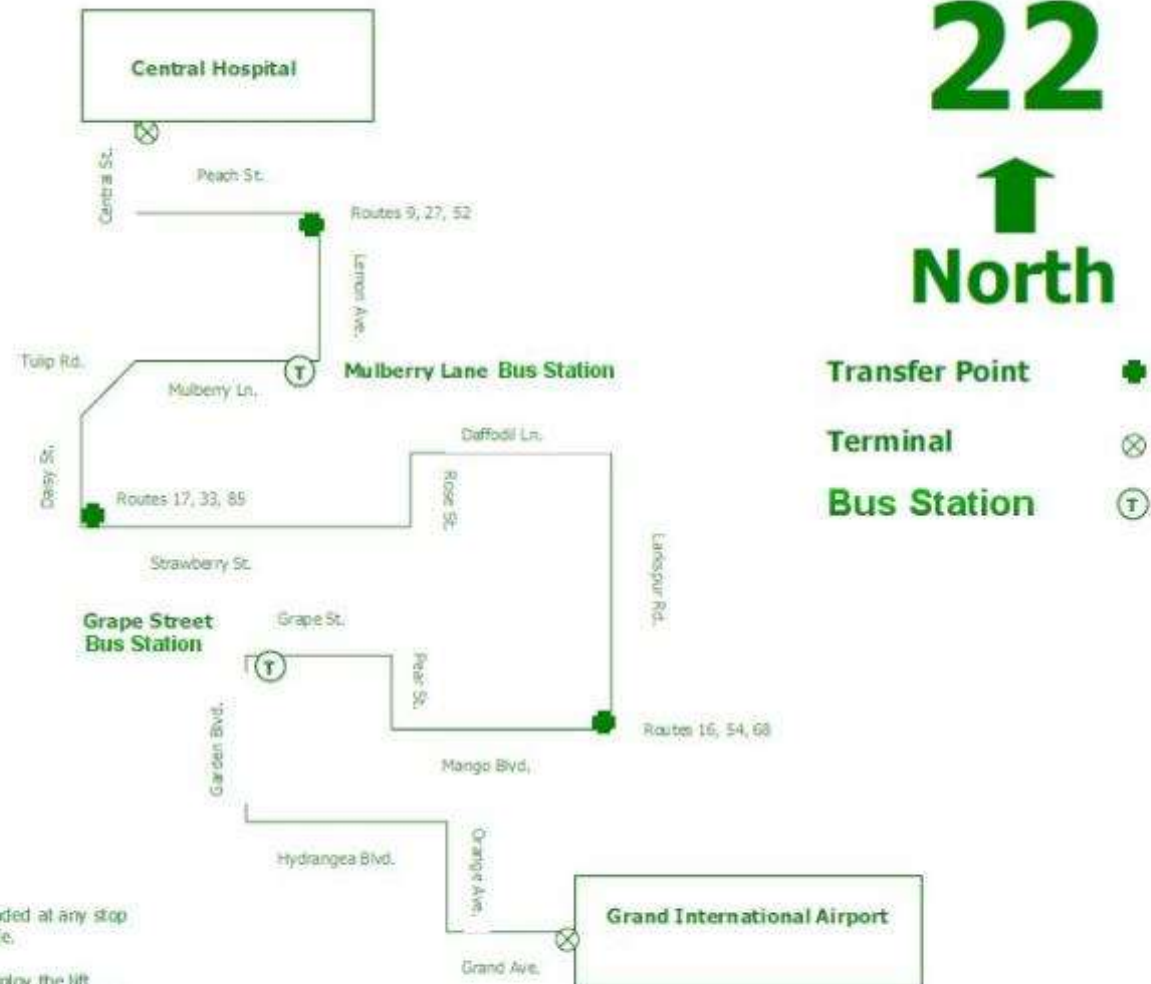


Mulberry Ln. Bus Station
Grape St. Bus Station

September 1, 2011

All buses are provided with bike racks
All buses provide wheelchair lift service

caused by delayed buses.



Bikes may be loaded/unloaded at any stop where it is feasible and safe.

Lift equipped buses will deploy the lift equipment at any stop where it is feasible and safe.

ROUTE 8

FARE INFORMATION

Fares and Schedules Subject to Change

FARES – Exact fare, please

Basic £2.00

Senior Citizen/Disabled £1.00

Children 5 and Under Free

PREPAID FARES

Token Pack

(11 tokens for the price of ten)

Tokens are good for fare only on buses

Monthly Ready Pass £54.00

Senior Citizen/Disabled £13.50

Youths (18 and under) £26.00

(ID may be requested)

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FAREBOXES: accept £1 notes, coins but do not give change.

PRIORITY SEATING: at the request of the driver, please reserve the seats at the front of the bus for Senior citizens and the Disabled.

ANIMALS: Trained guide dogs may accompany persons with disabilities. Other animals must be in an enclosed carrier and transported without assistance by the driver or operator. The carrier must be placed on the passenger's lap or under a seat.
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HOW TO USE THE BIKE BUS

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The schedules and other arrangements shown in the timetable are



**Eastgate Mall
State University**

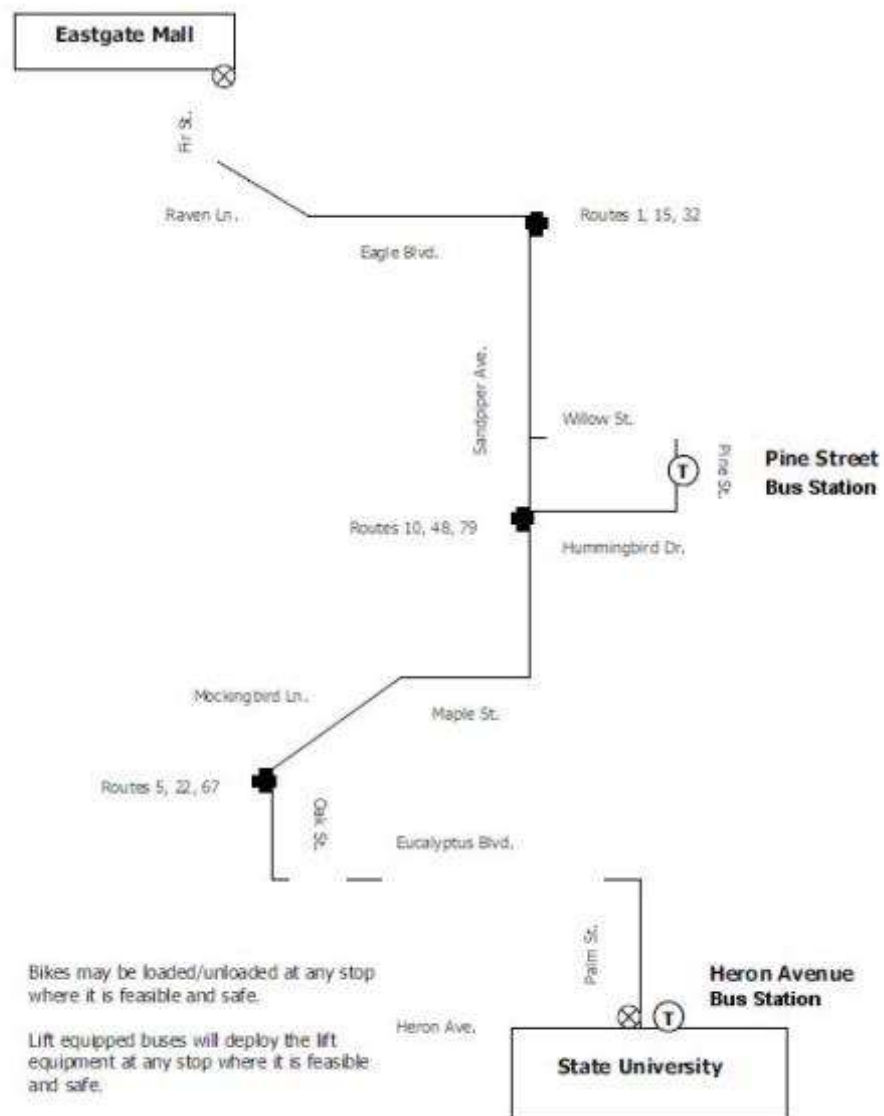
**Metropolitan Transit System
(MTS)**

Pine St. Bus Station
Heron Ave. Bus Station

September 1, 2011

All buses are provided with bike racks
All buses provide wheelchair lift service

subject to change. Metropolitan Transit does not assume responsibility for errors in timetables, nor for any inconvenience caused by delayed buses.



8

North

Transfer Point

Terminal

Bus Station

ROUTE 46

FARE INFORMATION

Fares and Schedules Subject to Change

FARES – Exact fare, please

Basic £2.00

Senior Citizen/Disabled £1.00

Children 5 and Under Free

PREPAID FARES

Token Pack

(11 tokens for the price of ten)

Tokens are good for fare only on buses

Monthly Ready Pass £54.00

Senior Citizen/Disabled £13.50

Youths (18 and under) £26.00

(ID may be requested)

@ Discounted passes made possible by Transnet

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SENIOR CITIZEN/DISABLED PASSENGERS: must show proof of eligibility (driving licence, DVLA Senior Citizen/Disabled card, pension or concessions cards upon request.

FAREBOXES: accept £1 notes, coins but do not give change.

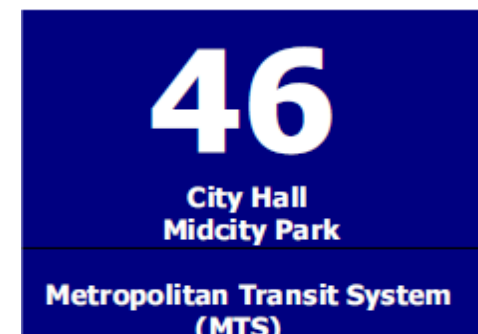
PRIORITY SEATING: at the request of the driver, please reserve the seats at the front of the bus for Senior citizens and the Disabled.

ANIMALS: Trained guide dogs may accompany persons with disabilities. Other animals must be in an enclosed carrier and transported without assistance by the driver or operator. The carrier must be placed on the passenger's lap or under a seat.
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The schedules and other arrangements shown in the timetable are



Main St. Bus Station
5th St. Bus Station

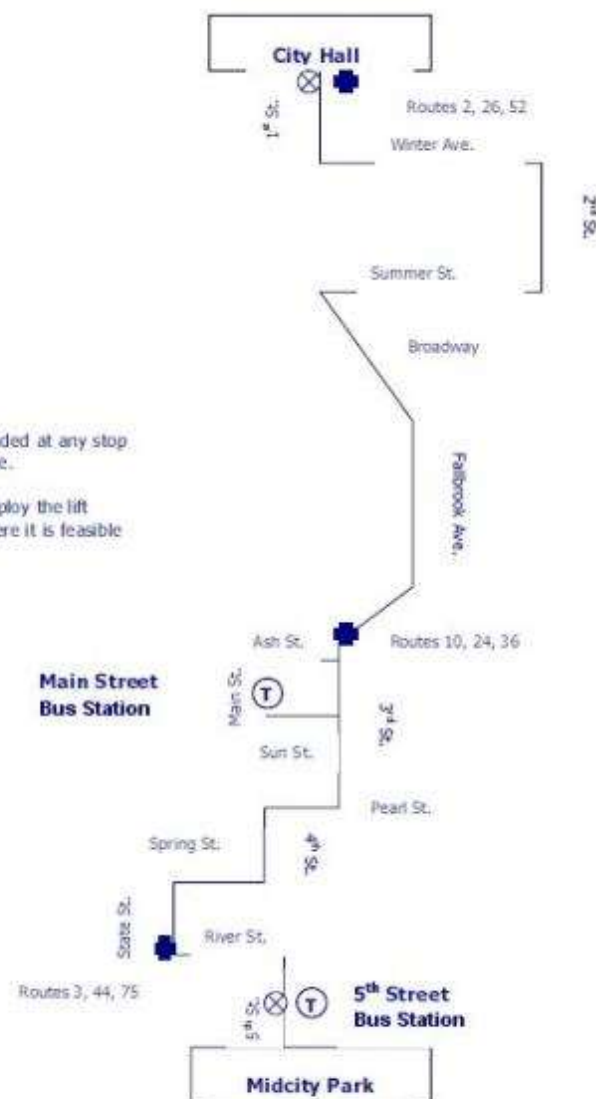
September 1, 2011

All buses are provided with bike racks
All buses provide wheelchair lift service

subject to change. Metropolitan Transit does not assume responsibility for errors in timetables, nor for any inconvenience caused by delayed buses.

Bikes may be loaded/unloaded at any stop where it is feasible and safe.

Lift equipped buses will deploy the lift equipment at any stop where it is feasible and safe.



46

↑
North

Transfer Point 

Terminal 

Bus Station 

ALTERNATE FORMATS ARE AVAILABLE UPON REQUEST

22

Central Hospital to Grand Airport

Grand Airport to Central Hospital

Monday through Friday

Central Hospital	Peach St. & Lemon Ave.	Lemon Ave. & Mulberry Ln.	Daisy St. & Strawberry St.	Larkspur Rd. & Mango Blvd.	Grand Ave. & Grand Airport	Grand Ave. & Grand Airport	Larkspur Rd. & Mango Blvd.	Daisy St. & Strawberry St.	Lemon Ave. & Mulberry Ln.	Peach St. & Lemon Ave.	Central Hospital
6:12 a	6:19 a	6:24 a	6:37 a	6:50 a	6:56 a	6:21 a	6:32 a	6:52 a	7:02 a	7:08 a	7:18 a
6:27	6:34	6:39	6:52	7:05	7:11	6:36	6:47	7:07	7:17	7:23	7:33
6:42	6:49	6:54	7:07	7:20	7:26	6:51	7:02	7:22	7:32	7:38	7:48
6:57	7:04	7:09	7:22	7:35	7:41	7:06	7:17	7:37	7:47	7:53	8:03
7:12	7:19	7:24	7:37	7:50	7:56	7:21	7:32	7:52	8:02	8:08	8:18
7:27	7:34	7:39	7:52	8:05	8:11	7:36	7:47	8:07	8:17	8:22	8:29
7:42	7:49	7:54	8:07	8:20	8:26	7:51	8:02	8:22	8:32	8:37	8:44
7:57	8:04	8:09	8:22	8:35	8:41	8:06	8:17	8:37	8:47	8:52	8:59
8:12	8:19	8:24	8:37	8:50	8:56	8:21	8:32	8:52	9:02	9:07	9:14
8:27	8:34	8:39	8:52	9:05	9:11	8:36	8:47	9:07	9:17	9:22	9:29
8:42	8:49	8:54	9:07	9:20	9:26	8:51	9:02	9:22	9:32	9:37	9:44
9:00	9:07	9:11	9:22	9:35	9:41	9:06	9:17	9:37	9:47	9:52	9:59
9:15	9:22	9:26	9:37	9:50	9:56	9:21	9:30	9:52	10:02	10:07	10:14
9:30	9:37	9:41	9:52	10:05	10:11	9:36	9:45	10:07	10:17	10:22	10:29
9:45	9:52	9:56	10:07	10:20	10:26	9:51	10:00	10:22	10:32	10:37	10:44
10:00	10:07	10:11	10:22	10:35	10:41	10:06	10:15	10:37	10:47	10:52	10:59
10:15	10:22	10:26	10:37	10:50	10:56	10:21	10:30	10:52	11:02	11:07	11:14
10:30	10:37	10:41	10:52	11:05	11:11	10:36	10:45	11:07	11:17	11:22	11:29
10:45	10:52	10:56	11:07	11:20	11:26	10:51	11:00	11:22	11:32	11:37	11:44
11:13	11:20	11:24	11:37	11:50	11:56	11:20	11:29	11:52	12:02 p	12:07 p	12:15 p
11:28	11:35	11:39	11:52	12:05 p	12:11 p	11:35	11:44	12:07 p	12:17	12:22	12:30
11:43	11:50	11:54	12:07 p	12:20	12:26	11:50	11:59	12:22	12:32	12:37	12:45
11:58	12:05 p	12:09 p	12:22	12:35	12:41	12:05 p	12:14 p	12:37	12:47	12:52	1:00
12:13 p	12:20	12:24	12:37	12:50	12:56	12:20	12:29	12:52	1:02	1:07	1:15
12:43	12:50	12:54	1:07	1:20	1:26	12:50	12:59	1:22	1:32	1:37	1:45
12:58	1:05	1:09	1:22	1:35	1:41	1:05	1:14	1:37	1:47	1:52	2:00
1:13	1:20	1:24	1:37	1:50	1:56	1:20	1:29	1:52	2:02	2:07	2:15
1:28	1:35	1:39	1:52	2:05	2:11	1:35	1:44	2:07	2:17	2:22	2:30
1:43	1:50	1:54	2:07	2:20	2:26	1:50	1:59	2:22	2:32	2:37	2:45
1:57	2:04	2:09	2:22	2:37	2:43	2:05	2:14	2:37	2:47	2:52	3:00
2:07	2:14	2:19	2:32	2:47	2:53	2:20	2:29	2:52	3:02	3:07	3:15
2:17	2:24	2:29	2:42	2:57	3:03	2:35	2:44	3:07	3:17	3:22	3:30
2:27	2:34	2:39	2:52	3:07	3:13	2:50	2:59	3:22	3:32	3:37	3:45
2:42	2:49	2:54	3:07	3:22	3:28	3:05	3:14	3:37	3:47	3:52	4:00
2:57	3:04	3:09	3:22	3:37	3:43	3:20	3:29	3:52	4:02	4:07	4:15
3:42	3:49	3:54	4:07	4:22	4:28	4:05	4:14	4:37	4:47	4:52	5:00
3:57	4:04	4:09	4:22	4:37	4:43	4:20	4:29	4:52	5:02	5:07	5:15
4:12	4:19	4:24	4:37	4:52	4:58	4:35	4:44	5:07	5:17	5:22	5:30
4:42	4:49	4:54	5:07	5:22	5:28	5:05	5:14	5:37	5:47	5:52	6:00
4:57	5:04	5:09	5:22	5:37	5:43	5:20	5:29	5:52	6:02	6:07	6:15
5:12	5:19	5:24	5:37	5:52	5:58	5:35	5:44	6:07	6:17	6:22	6:30
5:42	5:49	5:54	6:07	6:20	6:25	6:23	6:32	6:52	7:01	7:05	7:11
5:57	6:04	6:09	6:22	6:35	6:40	6:54	7:02	7:22	7:31	7:35	7:41
6:27	6:34	6:39	6:52	7:05	7:10	7:24	7:32	7:52	8:01	8:05	8:11
6:57	7:04	7:09	7:22	7:35	7:40	7:54	8:02	8:22	8:31	8:35	8:41
7:29	7:35	7:39	7:52	8:05	8:10	8:24	8:32	8:52	9:01	9:05	9:11
7:59	8:05	8:09	8:22	8:35	8:40	8:54	9:02	9:22	9:31	9:35	9:41
8:29	8:35	8:39	8:52	9:05	9:10	9:24	9:32	9:52	10:01	10:05	10:11
8:59	9:05	9:09	9:22	9:35	9:40	9:54	10:02	10:22	10:31	10:35	10:41

Saturdays, Sundays and Holidays

Central Hospital	Peach St. & Lemon Ave.	Lemon Ave. & Mulberry Ln.	Daisy St. & Strawberry St.	Larkspur Rd. & Mango Blvd.	Grand Ave. & Grand Airport	Grand Ave. & Grand Airport	Larkspur Rd. & Mango Blvd.	Daisy St. & Strawberry St.	Lemon Ave. & Mulberry Ln.	Peach St. & Lemon Ave.	Central Hospital
7:58	8:05	8:10	8:22	8:35	8:41	7:52	8:01	8:22	8:32	8:37	8:44
8:28	8:35	8:40	8:52	9:05	9:11	8:22	8:31	8:52	9:02	9:07	9:14
8:58	9:05	9:10	9:22	9:35	9:41	8:52	9:01	9:22	9:32	9:37	9:44

UPSA - FINANCIAL SKILLS: COUNTING CHANGE

Real money total: £4.03

✓ 1 ten pound note * **FAKE**

✓ 1 five pound note * **FAKE**

✓ 3 one pound coins

✓ 1 twenty pence piece

✓ 4 ten pence pieces

$\sqrt{7}$ five pence pieces

✓ 8 pennies

[illegible]

Appendix 2.7 – CAINS

1

CAINS (v1.0)

ID: _____ DATE: _____ RATER: _____

Overall Introduction: In this interview, I'll be asking you some questions about things you have been doing over the past week. In the first section, I'm going to ask you some questions about your family, romantic partners, and friends, including how motivated you have been to spend time with them and how you felt when you were around them.

I. SOCIAL (MOTIVATION & PLEASURE)

ITEM 1: MOTIVATION FOR CLOSE FAMILY/SPOUSE/PARTNER RELATIONSHIPS
[Note: Romantic relationships can be rated in either Item 1 or Item 2 but NOT both. A spouse/ partner relationship in which the couple is living together should be assessed in Item 1. A dating/romantic relationship in which the couple is not living together should be assessed in Item 2.]

The following questions are about your family. This can include relatives like parents, brothers or sisters and other relatives, as well as your spouse [if married] or live-in partner. Have you been in contact with or visited with any family members in the past week (in person, phone, email)? Any contact with a spouse or partner?

IF CONTACT:

- Who have you been in contact with? Anybody else?
- What things have you done with your family?
- IF RELEVANT: What things have you done with your spouse/partner?
- How much time did you spend together?

Behavior

- What have you done to see or contact your [family/spouse/partner] in the past week?
- When you were with your [family/spouse/partner] who decided what you would do?
- Who started the conversation? Did you start it? Did your [family/spouse/partner]? Were you involved in the conversation?
- Did you ever find that you quickly wanted to end your interactions with your [family/spouse/partner]? Did you want them to last longer?

Motivation & Interest in Closeness

- Have you been motivated to be around or in touch with your [family/spouse/partner] in the past week? (Why is that?)
- What did you talk about? Can you talk about good and bad times with your [family/spouse/partner]?
- How close do you feel to your [family/spouse/partner]? What does being close mean for you?
- Were there times in the past week when you just didn't want to be around or in touch with your [family/spouse/partner]?
- How important is being part of a family to you?
- What about that is important to you? Have you felt this way throughout the past week?

IF NO FAMILY CONTACT:
[NOTE: This section applies when not part of a close family or if available relatives could be contacted but person has chosen not to interact. If the person is not currently in a relationship with a live-in spouse/partner, interest in romantic relationships is assessed in Item 2.]

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2

- Has your family tried to contact you or visit you in the last week?
- Has anything kept you or held you back from being in contact with your family?
- Do you wish you were closer to your family? OR Do you wish you were part of a close family?
- Did you miss interacting with your family in the past week?
- Is having a relationship with your family important to you? What about having a relationship is important to you?
- Have you preferred to spend your time alone rather than with your family?

Item 1 – Motivation for Close Family/Spouse/Partner Relationships

0 = No impairment: VERY INTERESTED in and highly values close family bonds as one of the most important parts of life. Strongly desires and is highly motivated to be in contact with family. Regularly initiates and persists in interactions with family and actively engages in these interactions; good and bad times are openly discussed. Well within normal limits.

1 = Mild deficit: GENERALLY INTERESTED in and values close family bonds though response suggests some minor or questionable reduction. Generally desires and is motivated to maintain contact with family. Has a close relationship with family member(s) in which good and bad times can be discussed. Mild deficit in initiating and persisting in regular interactions with family – generally actively engaged when interactions occur.

2 = Moderate deficit: SOMEWHAT INTERESTED in family relationships and considers them somewhat important. May occasionally miss close connections with family but is only somewhat motivated to seek out interaction with family. Notable deficit in initiating and persistently engaging in interactions; discussion of good and bad times is limited. Interactions with family members may occur but are largely superficial and participation is best characterized as “going through the motions”; interactions are more likely initiated by family with mostly passive involvement of the person.

3 = Moderately severe deficit: LITTLE INTEREST in family relationships (could “take it or leave it”) and does not describe family bonds as important. Describes hardly any motivation and minimal effort to have close family relationships. Rarely has discussion of good and bad times with family members. Contact and engagement with family is superficial and passive with almost all initiation and efforts to engage coming from others.

4 = Severe deficit: NO INTEREST in family relationships and does not consider them at all important. Prefers to be alone and is not at all motivated to be with family. If person does see family, it is done so grudgingly, passively and with no interest.

ITEM 2: MOTIVATION FOR CLOSE FRIENDSHIPS & ROMANTIC RELATIONSHIPS
Let's talk about friends (and dating or romantic relationships) now. By friends, I mean people who you know and spend time with, anyone you consider a friend, or people you can rely on and count on. Have you had any contact with friends in the last week (in person, phone, email)? IF RELEVANT: have you been in contact with a romantic partner or dating in the last week?

IF CONTACT:

- In the past week, what have you done with your [friends/partner/dates]?
- Tell me about what you did [or what you talked about] during that [visit, activity, conversation]?
- How much time did you spend together with [friends/partners/dates]?

Behavior

- What steps did you take to see or contact your [friends/partner/dates] in the past week?
- When you were with your [friends/partner/dates], who decided what you would do?
- When you spoke with your [friends/partner/dates], who started the conversation? Did you?
- Did you ever find that you quickly wanted to end your interaction with your [friends/partner/dates]? Did you want them to last longer?

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Motivation & Interest in Closeness

- Have you been motivated to be around your friends (partner/dates) in the past week? Why is that?
- Can you talk about both good times and bad times?
- Were there times in the past week when you just didn't feel like being around your friends (partner/dates)?
- How important is having friendships (partner/dates) to you? What about that is important to you?
- How close do you feel to your friends (partner/dates)? What does being close mean for you?

IF NO FRIENDS/ROMANTIC CONTACT:

- Are you interested in having friends or dating?
- Is having friendships [or being in a romantic relationship] important to you? If Yes, what about [specify friendships/romantic partner] is important?
- Did you miss these types of relationships in the past week?
- Would you like to have friends [or a romantic partner] with whom you could talk about good and bad times?
- (If any indication of interest) Have you taken any steps to meet someone who might be a friend (or romantic partner)?
- Has anything kept you or held you back from being in contact with your friends?
- Would you prefer to have friendships [or a romantic relationship] or would you prefer to be alone?

Item 2 – Motivation for Close Friendships & Romantic Relationships

- 0 = No impairment:** VERY INTERESTED in and highly values friend/romantic relationships as one of the most important parts of life. Strongly desires and is very motivated to engage in friendships. Regularly initiates and persists in interactions with friends/partner and actively engages in these interactions; good and bad times are openly discussed. Well within normal limits.
- 1 = Mild deficit:** GENERALLY INTERESTED in and values friend/romantic relationships though response suggests some minor or questionable reduction. Generally desires and is motivated to engage in friendships. Has friendships/relationship in which good and bad times can be discussed though this may be less consistent. Mild deficit in initiating or persistently engaging during interactions with friends/partner. If no friends/relationship, misses friend/romantic relationships, is motivated to have friends/relationship, and makes efforts to seek out friends/relationship.
- 2 = Moderate deficit:** SOMEWHAT INTERESTED in friend/romantic relationships and considers them somewhat important. May occasionally miss close connections with friends/partner and is somewhat motivated to have friends/partner. Notable deficit in initiating and persistently engaging in interactions; discussion of good and bad times is limited. Interactions with friends/romantic partner may occur but are largely superficial and participation is best characterized as "going through the motions"; interactions are initiated by others with mostly passive involvement of the person. If no friend/romantic relationships, is only somewhat motivated to have friends/partner and rarely if ever seeks out friends/partner.
- 3 = Moderately severe deficit:** LITTLE INTEREST in friend/romantic relationships (could "take it or leave it") and does not describe friends/partner as important. Describes hardly any motivation to have friendships, and would just as soon be alone. Contact and engagement with others is superficial and passive with almost all initiation and efforts to engage coming from others.
- 4 = Severe deficit:** NO INTEREST in friend/romantic relationships and does not consider them at all important. Prefers to be alone and is not at all motivated to have friends/partner.

ITEM 3: FREQUENCY OF PLEASURABLE SOCIAL ACTIVITIES – PAST WEEK

[NOTE: Ratings are based on NUMBER OF DAYS IN THE WEEK that pleasurable activity with other people is experienced. When there are reports of several different activities occurring, clarify if these happened on same or different days.]

Now, I want to talk to you about how you felt during the times you spent with or were in contact with others during the past week. You can include times with any of the people we have talked about so far or anyone else. Did you have any enjoyable interactions with other people, such as:

- Family (PAUSE)
- Romantic or dating partners (PAUSE)
- Friends (PAUSE)
- Any other enjoyable social interactions or time spent with people? (PAUSE)
- IF NEEDED: Ask about people brought up in other sections that were described as enjoyable interactions

Sun	Mon	Tue	Wed	Thu	Fri	Sat

IF YES:

- What about that was enjoyable?
- How many days did you enjoy/get pleasure from these interactions [time spent with xx person(s)] (for each)?
- [If many (i.e., 5 or 6) days mentioned or if not clear which days of week interactions were enjoyed] Were there any days that you did not have enjoyable interactions with other people?

Item 3 – Frequency of Pleasurable Social Activities – Past Week

- 0 = No impairment:** Pleasure experienced daily.
- 1 = Mild deficit:** Pleasure experienced 5-6 days.
- 2 = Moderate deficit:** Pleasure experienced 3-4 days.
- 3 = Moderately severe deficit:** Pleasure experienced 1-2 days.
- 4 = Severe deficit:** No pleasure reported

ITEM 4: FREQUENCY OF EXPECTED PLEASURABLE SOCIAL ACTIVITIES – NEXT WEEK

[NOTE: Ratings are based on total NUMBER OF EXPECTED PLEASURABLE ACTIVITIES, regardless of days on which they are expected to occur].

Now I would like you to think ahead to NEXT week (next 7 days), thinking about whom you will spend time with. You can include people you have already talked about or anyone else. What do you think you will enjoy doing in the NEXT week with other people?

FOR EACH ANSWER PROVIDED:

- What about it do you expect to enjoy?
- How often do you think you will enjoy this in the next week?

FOLLOW UP

- Are there other experiences with people you think you will enjoy in the next week?

ITEM 4 – Frequency of Expected Pleasurable Social Activities – Next week

- 0 = No impairment:** Expecting MANY (7 or more) pleasurable experiences.
- 1 = Mild deficit:** Expecting enjoyment from SEVERAL (5-6) pleasurable experiences.
- 2 = Moderate deficit:** Expecting enjoyment from a FEW (3-4) pleasurable experiences.
- 3 = Moderately severe deficit:** Expecting a COUPLE (1-2) pleasurable experiences.
- 4 = Severe deficit:** Expecting NO pleasurable experiences.

II. WORK & SCHOOL (MOTIVATION & PLEASURE)

ITEM 5: MOTIVATION FOR WORK & SCHOOL ACTIVITIES

Now I am going to ask you some questions about work and school, including how motivated you have been for work or school activities and how you felt while doing these things over the past week. Have you been working or going to school over the past week? Any volunteer work? Are you in a work-related treatment program?

IF IN A RELEVANT ROLE:

- Tell me about what you do in your [insert role here]
- How much time has this involved over the past week?

Behavior

- Have you been able to complete tasks at [insert role here]?
- In the past week has anyone raised any concerns with your [insert role here] performance?
- Have you missed any days in the past week? Why?
- Does someone need to remind you about [insert role here]? Why is that?
- Were there things you meant to do or were supposed to do but just never got around to doing them? Why?

Motivation

- How do you feel about [insert role here]?
- Have you been motivated to do your [insert role here]?
- What motivates you to do your [insert role here]?
- Were there times during the past week when you just didn't feel like [insert role here]?
- How important is your [insert role here] to you? What about it is important?

IF NO CURRENT ROLE:

- Is there a reason why you are not currently (work/school/volunteer)?
- Has anything held you back from looking for (work/school/volunteer)?
- How do you feel about working or going to school or volunteering?
- Have you felt much interest in work/school/volunteer? (Tell me more)
- Is working important to you? What about working/going to school/volunteering is important?
- Do you miss work/school/volunteer?
- Have you tried to take any steps to start working/going to school/volunteering? What steps have you taken? How often have you looked into work/school/volunteer?

ITEM 5 – Motivation for Work & School Activities

- 0 = No impairment: Person is VERY MOTIVATED to seek out work or school, or new opportunities in work or school; initiates and persists in work, school, or job-seeking on a regular basis. Well within normal limits.
- 1 = Mild deficit: Person is GENERALLY MOTIVATED to seek out work or school or new opportunities in work or school; a mild deficit in initiating and persisting; may report instances of initiating, but with moderate persistence.
- 2 = Moderate deficit: Person is SOMEWHAT MOTIVATED to seek out work or school or new opportunities in work or school; notable deficit in initiating; may have initiated activities, but needed reminders on multiple occasions, and/or not initiated any new activities, and/or not persisted for very long.
- 3 = Moderately severe deficit: Person is only SLIGHTLY MOTIVATED to seek out work or school or new opportunities in work or school; significant deficit in initiating; may have needed constant reminders, and/or initiated a few activities; did not persist for very long.
- 4 = Severe deficit: Person is NOT AT ALL MOTIVATED to seek out work / school; nearly total lack of initiation and persistence in work, school, or job seeking.

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ITEM 6: FREQUENCY OF EXPECTED PLEASURABLE WORK & SCHOOL ACTIVITIES - NEXT WEEK

[NOTE: Ratings are based on total NUMBER OF EXPECTED PLEASURABLE ACTIVITIES, regardless of days on which they are expected to occur].

Now I would like you to think ahead to NEXT week (next 7 days); thinking about work/volunteer/school.

IF HAS A RELEVANT ROLE:

- What do you think you will enjoy doing in the NEXT week at work/volunteer/school, etc.

IF NO RELEVANT ROLE:

- Do you think you will enjoy anything related to seeking paid or volunteer work, or school?

FOR EACH ANSWER PROVIDED:

- What about it do you expect to enjoy?
- How often do you think you will enjoy this in the next week?

FOLLOW UP:

- Are there other work/school experiences you think you will enjoy in the next week?

ITEM 6 – Frequency of Expected Pleasurable Work & School Activities – Next Week

- 0 = No impairment: Expecting MANY (7 or more) pleasurable experiences.
- 1 = Mild deficit: Expecting enjoyment from SEVERAL (5-6) pleasurable experiences.
- 2 = Moderate deficit: Expecting enjoyment from a FEW (3-4) pleasurable experiences.
- 3 = Moderately severe deficit: Expecting a COUPLE (1-2) pleasurable experiences.
- 4 = Severe deficit: Expecting NO pleasurable experiences.

III. RECREATION (MOTIVATION & PLEASURE)

ITEM 7: MOTIVATION FOR RECREATIONAL ACTIVITIES

In the next section, I am going to ask you some questions about what you do in your free time – any hobbies or recreational activities. I will ask about your motivation and feelings about the things that you have done in your free time over the past week.

- What have you done in your free time in the past week?
- Have you participated in any hobbies or leisure activities such as sports or games, going to church, TV, music, reading, internet, walking or other such activities during the past week?

IF YES:

Behavior

- Tell me about (activity). How much time has this involved over the past week? Did you want to do (activity) more than that? Did it last longer than you had hoped? Why did it only last for (xx)?
- Did anything get in the way of doing these activities over the past week? What was that?
- Who initiated these activities? Did someone need to remind you to participate in these activities?

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Motivation

- How has your motivation or drive to get involved in these activities been over the past week?
- Did you ever feel like you just weren't very interested in these activities?
- Are these types of activities important to you? Why? Have you been interested in these activities?
- Did you ever feel that you would just as soon do nothing instead of getting involved in these types of activities?

IF NO:

- Is there a reason why you haven't gotten involved in any hobbies or recreational activities in the past week?
- Have you wanted to or were you motivated to do something with your free time in the past week?
- Did anything ever get in the way of doing these types of activities over the past week? What was that?

ITEM 7 – Motivation for Recreational Activities

- 0 = No impairment: Person is VERY MOTIVATED to seek out hobbies and recreational activities; initiates and persists in hobbies and recreational activities on a regular basis, well within normal limits.
- 1 = Mild deficit: Person is GENERALLY MOTIVATED to seek out hobbies and recreational activities; a mild deficit in initiating and persisting; may report initiating hobbies, but with moderate persistence.
- 2 = Moderate deficit: Person is SOMEWHAT MOTIVATED to seek out hobbies and recreational activities; notable deficit in initiating; may have initiated some activities and/or not persisted for very long. Others were somewhat more likely to initiate hobbies or activities.
- 3 = Moderately severe deficit: Person is only SLIGHTLY MOTIVATED to seek out hobbies and recreational activities; significant deficit in initiating and persisting; may have initiated a few activities and not persisted for very long. Others were much more likely to initiate hobbies or prompt initiation.
- 4 = Severe deficit: Person is NOT AT ALL MOTIVATED to seek out hobbies and recreational activities; nearly total lack of initiation and persistence in hobbies or recreational activities.

ITEM 8: FREQUENCY OF PLEASURABLE RECREATIONAL ACTIVITIES – PAST WEEK

[NOTE: Rating is based on both VARIETY of pleasurable activities and DAILY FREQUENCY that these are experienced. When there are reports of several different activities occurring, need to clarify if these happened on same or different days.]

Did you have any enjoyable (pleasurable) experience from things you did in your free time last week? You can include any of the activities we've talked about so far or any other leisure activities in the past week, including TV, sports or games, going to church, music, reading, internet, walking or other such activities?

- What about [insert activity here] was enjoyable?
- How many days did you enjoy/get pleasure from these experiences?
- IF NEEDED: Ask about activities brought up in other sections that were described as enjoyable

FOLLOW UP:

Any other enjoyable experiences from things you do in your free time or your hobbies?

Activity	Sun	Mon	Tue	Wed	Thu	Fri	Sat

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ITEM 8 – Frequency of Pleasurable Recreational Activities - Past Week

- 0 = No impairment: At least A FEW (3) different types of pleasurable experiences, experienced daily.
- 1 = Mild deficit: At least A FEW (3) different types of pleasurable experiences, experienced more days than not.
- 2 = Moderate deficit: 1 or 2 different types of pleasurable experiences, experienced more days than not.
- 3 = Moderately severe deficit: 1 type of pleasurable experience, experienced on just a few days.
- 4 = Severe deficit: No pleasurable experiences.

ITEM 9: FREQUENCY OF EXPECTED PLEASURABLE RECREATIONAL ACTIVITIES – NEXT WEEK

[NOTE: Ratings are based on total NUMBER OF EXPECTED PLEASURABLE ACTIVITIES, regardless of days on which they are expected to occur]

Now I would like you to think ahead to NEXT week (next 7 days), thinking about your free time/hobbies/ recreation. You can include any of the activities you have already talked about or anything else. What do you think you will enjoy doing in the NEXT WEEK in your recreational/free time?

FOR EACH ANSWER PROVIDED:

- What about it do you expect to enjoy?
- How often do you think you will enjoy [activity] in the next week?

FOLLOW UP:

- Are there other things you do in your free time like hobbies or recreational activities that you think you will enjoy in the next week?

ITEM 9 – Frequency of Expected Pleasurable Recreational Activities – Next Week

- 0 = No impairment: Expecting MANY (7 or more) pleasurable experiences.
- 1 = Mild deficit: Expecting enjoyment from SEVERAL (5-6) pleasurable experiences.
- 2 = Moderate deficit: Expecting enjoyment from a FEW (3-4) pleasurable experiences.
- 3 = Moderately severe deficit: Expecting a COUPLE (1-2) pleasurable experiences.
- 4 = Severe deficit: Expecting NO pleasurable experiences.

IV. EXPRESSION

ITEM 10: FACIAL EXPRESSION

When making the facial expression rating, consider facial movements across all parts of the face, including in the eyes (e.g., raised brows when surprised), mouth (smiling or grimacing), and mid-face (e.g., wrinkled nose when disgusted).

ITEM 10 - Facial Expression

- 0 = No impairment: WITHIN NORMAL LIMITS; frequent expressions throughout the interview.
- 1 = Mild deficit: MILD DECREASE in the frequency of facial expressions, with limited facial expressions during a few parts of the interview.
- 2 = Moderate deficit: NOTABLE DECREASE in the frequency of facial expressions, with diminished facial expressions during several parts of the interview.
- 3 = Moderately severe deficit: SIGNIFICANT LACK of facial expressions, with only a few changes in facial expression throughout most of the interview.
- 4 = Severe deficit: NEARLY TOTAL LACK of facial expressions throughout the interview.

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ITEM 11: VOCAL EXPRESSION

This item refers to prosodic features of the voice. This item reflects changes in tone during the course of speech. Speech rate, amount, or content of speech is not assessed.

Item 11 - Vocal Expression

- 0 = **No impairment:** WITHIN NORMAL LIMITS. Normal variation in vocal intonation across interview. Speech is expressive and animated.
- 1 = **Mild deficit:** MILD DECREASE in vocal intonation. Variation in intonation occurs with a limited intonation during a few parts of the interview.
- 2 = **Moderate deficit:** NOTABLE DECREASE in vocal intonation. Diminished intonation during several parts of the interview. Much of speech is lacking variability in intonation but prosodic changes occur in several parts of the interview.
- 3 = **Moderately severe deficit:** SIGNIFICANT LACK of vocal intonation with only a few changes in intonation throughout most of the interview. Most of speech is flat and lacking variability, only isolated instance of prosodic change.
- 4 = **Severe deficit:** NEARLY TOTAL LACK OF change in vocal intonation with characteristic flat or monotone speech throughout the interview.

ITEM 12: EXPRESSIVE GESTURES

Expressive gestures are used to emphasize what is communicated verbally through gestures made with the hands, head (nodding), shoulders (shrugging), and trunk (leaning forward, leaning back).

ITEM - 12 Expressive Gestures

- 0 = **No impairment:** WITHIN NORMAL LIMITS; uses frequent gestures throughout the interview.
- 1 = **Mild deficit:** MILD DECREASE in the frequency of expressive gestures, with limited gestures in a few parts of the interview.
- 2 = **Moderate deficit:** NOTABLE DECREASE in the frequency of expressive gestures, with lack of gestures during several parts of the interview.
- 3 = **Moderately severe deficit:** SIGNIFICANT LACK of expressive gestures, with only a few gestures throughout most of the interview.
- 4 = **Severe deficit:** NEARLY TOTAL LACK of expressive gestures.

ITEM 13: QUANTITY OF SPEECH

This item refers to the quantity of words spoken. Other speech abnormalities, such as disorganization, neologisms, or psychotic content are not rated here. For instance, a disorganized person may produce a large quantity of speech and have a low (normal) score on this item.

ITEM - 13 Quantity of speech

- 0 = **No impairment:** NORMAL AMOUNT of speech throughout the interview. Replies provide sufficient information with frequent spontaneous elaboration.
- 1 = **Mild deficit:** MILD DECREASE in the quantity of speech, with brief responses during a few parts of the interview.
- 2 = **Moderate deficit:** NOTABLE DECREASE in speech output, with brief responses during several parts of the interview.
- 3 = **Moderately severe deficit:** SIGNIFICANT LACK of speech, with very brief answers (only several words) in responses throughout most of the interview.
- 4 = **Severe deficit:** All or nearly all replies are one or two words throughout the entire interview.

Appendix 2.8 – CORE

CLINICAL
OUTCOMES in
ROUTINE
EVALUATION

**OUTCOME
MEASURE**

Site ID

letters only numbers only

Client ID

Therapist ID numbers only (1) numbers only (2)

Sub codes

Date form given

Age

Male ☐

Female ☐

Stage Completed

S Screening
R Referral
A Assessment
P First Therapy Session
P Pre-therapy (unspecified)
D During Therapy
L Last therapy session
X Follow up 1
Y Follow up 2

Stage

Episode

IMPORTANT - PLEASE READ THIS FIRST

This form has 34 statements about how you have been OVER THE LAST WEEK.
Please read each statement and think how often you felt that way last week.
Then tick the box which is closest to this.
Please use a dark pen (not penoil) and tick clearly within the boxes.

Over the last week	Not at all	Only occasionally	Sometimes	Often	Most or all the time	OFFICE USE ONLY
1 I have felt terribly alone and isolated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	F
2 I have felt tense, anxious or nervous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	P
3 I have felt I have someone to turn to for support when needed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	F
4 I have felt O.K. about myself	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	W
5 I have felt totally lacking in energy and enthusiasm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	P
6 I have been physically violent to others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R
7 I have felt able to cope when things go wrong	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	F
8 I have been troubled by aches, pains or other physical problems	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	P
9 I have thought of hurting myself	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R
10 Talking to people has felt too much for me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	F
11 Tension and anxiety have prevented me doing important things	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	P
12 I have been happy with the things I have done.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	F
13 I have been disturbed by unwanted thoughts and feelings	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	P
14 I have felt like crying	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	W

Please turn over

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Over the last week		Not at all	Only occasionally	Sometimes	Often	Most or all the time	OR/DO NOT USE ONLY
15	I have felt panic or terror	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> P
16	I made plans to end my life	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> R
17	I have felt overwhelmed by my problems	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> W
18	I have had difficulty getting to sleep or staying asleep	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> P
19	I have felt warmth or affection for someone	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> F
20	My problems have been impossible to put to one side	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> P
21	I have been able to do most things I needed to	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> F
22	I have threatened or intimidated another person	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> R
23	I have felt despairing or hopeless	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> P
24	I have thought it would be better if I were dead	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> R
25	I have felt criticised by other people	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> F
26	I have thought I have no friends	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> F
27	I have felt unhappy	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> P
28	Unwanted images or memories have been distressing me	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> P
29	I have been irritable when with other people	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> F
30	I have thought I am to blame for my problems and difficulties	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> P
31	I have felt optimistic about my future	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> W
32	I have achieved the things I wanted to	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> F
33	I have felt humiliated or shamed by other people	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> F
34	I have hurt myself physically or taken dangerous risks with my health	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> R

THANK YOU FOR YOUR TIME IN COMPLETING THIS QUESTIONNAIRE

Total Scores	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	→	<input type="text"/>	→	<input type="text"/>
Mean Scores (Total score for each dimension divided by number of items completed in that dimension)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>		<input type="text"/>		<input type="text"/>
	(W)	(P)	(F)	(R)		All items		All minus R

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Appendix 2.9 – Feedback form



CACR Training Feedback Questionnaire

We would like you to answer some questions about the training that you have participated in. The results will be used to plan future training. We do not ask for any identifying information and your response will remain anonymous.

Please circle your answer.

1. How much did you enjoy these sessions?

1 2 3 4 5

Did not enjoy at all

Really enjoyed

2. Did you find the Training sessions?

1 2 3 4 5

Not at all interesting

Highly interesting

3. Do you feel that you the training has improved your ability to pay attention?

1 2 3 4 5

No, no at all

Yes, lots

4. Do you feel that you the training has improved your memory?

1 2 3 4 5

No, no at all

Yes, lots

5. Was the length of sessions? *Please tick the appropriate box*

Too short ☐ Just right ☐ Too long ☐

6. Was the number of sessions per week right?

Too few ☐ Just right ☐ Too many ☐

How much did you enjoy each of the following activities?

7. Alertness Training



1 2 3 4 5
Did not enjoy at all Really enjoyed

8. Vigilance Training



1 2 3 4 5
Did not enjoy at all Really enjoyed

9. Selective Attention Training



1 2 3 4 5
Did not enjoy at all Really enjoyed

Please turn over page

10. Focused Attention Training



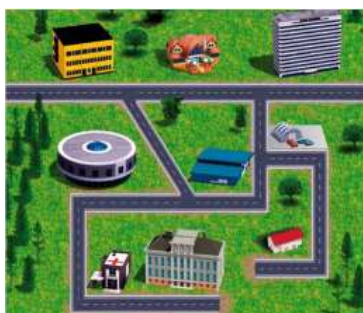
1 2 3 4 5
Did not enjoy at all Really enjoyed

11. Memory Training



1 2 3 4 5
Did not enjoy at all Really enjoyed

12. Planning Training



1 2 3 4 5
Did not enjoy at all Really enjoyed

Please turn over page

Please answer the following questions about the Computer Training:

What did you like about the training?

What are the good things that you will take away from the training?

How have you benefited from the training?

What did you dislike about the training?

What did you find difficult?

Can you think of anything to make the training better?

In the future, how likely would you be to recommend Cogniplus Training to other patients?

1

2

3

4

5

Would definitely **not** recommend

Would definitely recommend

Thank you for taking the time to complete the questionnaire.

Appendix 2.10 – Research phase approval documents

Letter confirming IRAS approval

Lothian NHS Board

South East Scotland Research
Ethics Committee 01



Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Telephone 0131 536 9000
Fax 0131 465 5789

www.nhslothian.scot.nhs.uk

Date: 16 August 2012
Your Ref:
Our Ref:

Enquiries to: Sandra Wylie
Extension: 35679
Direct Line: 0131 465 5679
Email: Sandra.Wylie@nhslothian.scot.nhs.uk

Dr Suzanne O'Rourke
Consultant Forensic Clinical
Neuropsychologist
The State Hospital,
8 Lampits Rd
Carstairs
Lanark
ML11 8RP

Dear Dr O'Rourke

Study title: A pilot study of Computer Assisted Cognitive
Remediation in mentally disordered offenders
REC reference: 12/SS/0134

Thank you for your letter of 13 August 2012, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a sub-committee of the REC. A list of the sub-committee members is attached.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the



Headquarters
Waverley Gate, 2-4 Waterloo Place, Edinburgh EH1 3EG

Chair Dr Charles J Whelan
Interim Chief Executive Tim Davison
Lothian NHS Board is the common name of Lothian Health Board

Letter from the State Hospital R&D Manager confirming conditional approval

Dr Suzanne O'Rourke
Consultant Forensic Clinical Neuropsychologist
The State Hospital

Thursday 14th of June 2012

Dear Suzanne,

Re: Research Proposal: A pilot study to examine the efficacy of Computer Assisted Cognitive Remediation in mentally disordered offenders.

Many thanks for your research proposal that was reviewed by the TSH Research Committee on Thursday the 31st of May 2012. The committee found the proposal to be an interesting piece of work, and are happy to approve the study subject to a few minor clarifications. These are as follows:

- The lengthy assessment process for each participant is of concern and this needs to be explained more fully in the information sheet.
- The study requires evidence of line manager sign off, and given study history the committee would like the proposal to be seen and supported by the Senior Management Team.
- The proposal does not address ethical approval requirements or intended process to define ethical approval requirements.
- No details are provided on the manner in which the study data will be analysed, or the way in which attribution can be defined to CACR given range of other interventions ongoing with the patient participants.
- The committee are concerned that there is a high likelihood of sample attrition given the lengthy assessment requirements and would like to know how the study team intend to address this given that the study employs a small sample size to start with.
- The committee would also be keen to see a simple study timetable with planned start and end dates built in and linked to study stages.

The committee also appreciates that the psychology dept are keen to commence the cognitive remediation work, and are subsequently willing to approve the study out with the regular research committee meetings as long as the clarifications and actions above are addressed. If you require any further assistance, or have any feedback on the Research approval process then please do not hesitate to contact me.

Yours sincerely



JAMIE PITCAIRN
Research & Development Manager
The State Hospital

Email from the State Hospital R&D Manager confirming conditions have been met

From: Pitcairn Jamie (STATE HOSPITALS BOARD FOR SCOTLAND)
Sent: 01 October 2012 12:24
To: hartley james (STATE HOSPITALS BOARD FOR SCOTLAND); O'Rourke Suzanne
(STATE HOSPITALS BOARD FOR SCOTLAND)
Cc: Gallagher Martin (NHS Lothian)
Subject: RE: State Hospital Computer Assisted Cognitive Remediation
-
Symptom Measure amendment

Dear James,

I have had a look over your IRAS substantial amendment and the amended proposal and have no initial concerns over this. The action you have taken directly relates to previous Research Committee feedback so on that basis we are grateful that you have taken the time to consider your options and while the CAINS takes slightly longer than the negative symptom part of the PANSS we appreciate that it is still less than was originally outlined within your proposal. Subsequently I am happy that you progress on this basis and I will ensure that your amendment is included on the next RC agenda.

Best wishes
Jamie

Jamie Pitcairn
R&D Manager
The State Hospital
01555 840293 Ext: 4355

-----Original Message-----

From: hartley james (STATE HOSPITALS BOARD FOR SCOTLAND)
Sent: 26 September 2012 12:22
To: O'Rourke Suzanne (STATE HOSPITALS BOARD FOR SCOTLAND); Pitcairn Jamie (STATE HOSPITALS BOARD FOR SCOTLAND)
Cc: Gallagher Martin (NHS Lothian)
Subject: FW: State Hospital Computer Assisted Cognitive Remediation
- Symptom Measure amendment

Jamie/Suzanne,

During the approval process for CACR study The State Hospital Research Committee asked if the length of patients' assessments might be reduced. As part of our response to this request we altered our methodology to indicate that only the negative subscale of the Positive and Negative Syndrome Scale (PANSS) would be administered as was the case in some previously reported literature. Subsequently we have discovered that, although previous studies reported only negative subscale results, they had in fact administered the entire assessment. It is not possible to reduce the length of the assessment itself to focus on negative symptoms only. As a result of this discovery we erred on the side of caution

and did not administer a measure of negative symptoms to patients during the pre control period assessment but would like to resolve this question before the pre-treatment assessments commence. We have approached the University of Edinburgh Sponsor, Ray French, who has indicated his approval for a proposed amendment below.

We are mindful that the original request to reduce the length of patient assessments was a very helpful suggestion and have therefore identified an alternative measure which we hope will meet our needs as a replacement for the PANSS. The Clinical Assessment Interview for Negative Symptoms (CAINS) is a new measure specifically designed for the assessment of negative symptoms in patients with a diagnosis of schizophrenia. It is endorsed by the National Institute of Mental Health's initiative 'Measurement and Treatment Research to Improve Cognition in Schizophrenia' and takes 30 minutes to administer.

We would appreciate your approval to proceed on the basis of this amendment. I attach the relevant IRAS and protocol forms (with amended text in bold). Could you please let me know when I can expect to hear from you on this as we have timetabled CAINS sessions to run next week and would appreciate an early response. I have received approval to proceed from the University sponsor, Ray French (please see below) and have asked the SSREC committee to let me have their decision.

Many thanks

James
Ex 4409

Appendix 2.11 – Participant information sheet and consent form

Participant information sheet

The State Hospital

Carstairs
Lanark
ML11 8RP
Telephone 01555 840293
Fax 01555 840024
<http://tsh.scot.nhs.uk>



Information Sheet

A study of whether practice on ‘computer video-game like’ exercises help the memory, attention and social functioning of patients at the State Hospital¹

We would like to invite you to take part in a research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. We will go through the information sheet with you and answer any questions you have.

Many patients at the State Hospital find that their illnesses, previous injuries or alcohol or drug abuse have affected their thinking. Many notice that they find it harder to remember things or concentrate. The hospital wants to try a new treatment that might help improve these symptoms. It's called Cogniplus and is just like playing a computer game. It is specially designed to help patients with these difficulties.

Your clinical team have referred you for this treatment which is why we have come along to talk about it today.

To see if the treatment works we are researching it by assessing how you are before and after taking part. Please read this leaflet and ask as many questions as you would like. You might like to talk to your key worker about it too.

Why have I been chosen?

Your clinical team think that because of your illness or medical history you may benefit from this treatment.

Do I have to take part?

No, it is up to you to decide whether to take part. If you do decide to take part you will be asked to sign a form to say this. Even if you sign the form you can still stop taking part at any time and without giving anyone a reason. If you don't want to take part or change your mind later it won't affect the rest of the treatment or change your care in any way.

What will happen to me if I take part?

If you decide to take part you will be asked to:-

- Complete an assessment, made up of a number of exercises and puzzles six times over the next 18 months. We will spread each assessment over a few meetings so that we never keep you for more than an hour and will seek to minimise the amount of

¹ The formal title of this research is 'A randomised controlled trial of Computer Assisted Cognitive Remediation in mentally disordered offenders'

time it takes for you to complete these exercises and puzzles. We will also meet with you to discuss your mood and how you are feeling about things. This will be a short interview lasting around 30 minutes. Research has shown that people who take part in these type of specialist computer games find it leads to improvements in their well being and motivation to do things.

- Play the specially designed computer games in the interview room on the ward. This will be for about 45 minutes every Monday, Wednesday and Friday for 14 weeks.

What are the possible benefits of taking part?

We hope that taking part in the treatment will improve your memory, concentration, how good you are at working things out and how you get on with other people. By taking part you will also help us know if the treatment works and whether the hospital should buy enough systems to offer it to everyone.

Will my taking part in this study be kept confidential?

Yes, All information you provide to us will be kept confidential. The results will be put into your notes and a summary sent to your clinical team. Only the researchers and your clinical team will have access to this information. The confidentiality of participants' personal data will be respected and protected in line with Data Protection Act 1998.

Your name, and anything that lets us know who you are, will be deleted before we look at the results to see if the treatment works.

What will happen to the results of the research study?

The results will be reported back to the hospital so that they know whether the treatment works and should be offered on all the wards. The results will also be included in two clinical psychology theses which will be stored in the University of Edinburgh's Library and in journal articles. Apart from the notes in your files, your name will not be on anything so no one will know that you took part or what your results were.

After your first assessment you will be given a summary of your results that you can keep. We will help you update this each time you are re-assessed and discuss how you are doing with you. You will also receive feedback on how well you are doing every time you use the computer. At the very end of the project we will describe our findings about whether the treatment works at the ward meeting.

Who is organising and funding the research?

The research is being conducted by the hospital as part of the neuropsychology service by two students who will use the results for their studies.

Who has reviewed the study?

The State Hospital Research Committee and the [South East Scotland] Research Ethics Committees have reviewed this study.

Contact for Further Information

If you would like any further information or have any questions please do not hesitate to contact us: James Hartley/Martin Gallagher on (x4473) or our supervisor Dr Suzanne O'Rourke x2089 (Tuesdays and Wednesdays).

Thank you for taking the time to read this.

The State Hospital

Carstairs
Lanark
ML11 8RP
Telephone 01555 840293
Fax 01555 840024
<http://tsh.scot.nhs.uk>



Participant consent form

Patient Identification Number for this trial:

CONSENT FORM

Title of Project: A pilot of Computer Based Cognitive Rehabilitation in mentally disordered offenders.

Name of Researchers: James Hartley/Martin Gallagher Please Initial

1. I confirm that I have read and understand the information sheet dated 25/06/2012 for the above study. I have had the chance to consider the information, ask questions and have had these answered so that I now feel I understand everything. ☐
2. I understand that it is up to me whether I take part and that I can drop out at any time without giving any reason and without it affecting the care I get. ☐
3. I understand that the researchers need to look at my medical notes if it is needed for the research. I give permission for the researchers to have access to my records. ☐
4. I agree to my RMO being informed about my participation in this study. ☐
5. I agree to take part in the above study. ☐

Name of Patient

Date

Signature

Name of Person taking consent

Date

Signature

Appendix 2.12 – Service evaluation phase approval documents

Confirmation of ethical approval from University of Edinburgh

Martin Gallagher
Flat 5, 704 Edgefauld Road
Springburn
Glasgow
G21 4NB



15 May 2013

Dear Martin,

Application for Level 2/3 Approval

Re: Computer Assisted Cognitive Remediation Therapy in a High Secure Forensic Psychiatric
Setting: A service evaluation

Thank you for submitting the above research project for review by the Section of Clinical Psychology Ethics Research Panel. I can confirm that the submission has been independently reviewed and was approved on the 13th May 2013.

Should there be any change to the research protocol it is important that you alert us to this as this may necessitate further review.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'K. Gardner', is written over a horizontal line.

Kirsty Gardner
Secretary
Clinical Psychology

Confirmation of service evaluation status from NHS

South East Scotland Research Ethics Service

Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG



Name: Martin Gallagher
Address: Arran Hub
The State Hospital
110 Lampits Road
Carstairs

Date: 13/05/2013
Your Ref:
Our Ref: NR/1304AB9
Enquiries to: Alex Bailey
Direct Line: 0131 465 5679
Email: alex.bailey@nhslothian.scot.nhs.uk

Dear Martin,

Project Title: Computer Assisted Cognitive Remediation Therapy in a High Secure Forensic Psychiatric Setting: A service evaluation

You have sought advice from the South East Scotland Research Ethics Service on the above project. This has been considered by the Scientific Officer and you are advised that, based on the submitted documentation (email correspondence and Thesis Ethics Form - Martin Gallagher - 19 April 2013.doc), it does not need NHS ethical review under the terms of the Governance Arrangements for Research Ethics Committees (A Harmonised Edition).

The advice is based on the following:

- *The project is limited to using data obtained as part of usual care, but note the requirement for Caldicott Guardian approval for the use or transfer of person-identifiable information within or from an organisation*

If the project is considered to be research you may require ethical approval as outlined in The Research Governance Framework for Health and Community Care. You may wish to contact your employer or professional body to arrange this. You may also require NHS management permission from host care organisations (R&D approval). You should contact the relevant NHS R&D departments to organise this.

For projects that are not research and will be conducted within the NHS you should contact the relevant local clinical governance team who will inform you of the relevant governance procedures required before the project commences.

This letter should not be interpreted as giving a form of ethical approval or any endorsement of the project, but it may be provided to a journal or other body as evidence that NHS ethical approval is not required. However, if you, your sponsor/funder feels that the project requires ethical review by an NHS REC, please write setting out your reasons and we will be pleased to consider further. You should retain a copy of this letter with your project file as evidence that you have sought advice from the South East Scotland Research Ethics Service.

Yours sincerely,

Alex Bailey
Scientific Officer
South East Scotland Research Ethics Service



1

Headquarters
Waverley Gate, 2-4 Waterloo Place, Edinburgh EH1 3EG

Chair Dr Charles J Winstanley
Chief Executive Tim Dawson
Lothian NHS Board is the common name of Lothian Health Board

Letter informing the State Hospital Research Committee of Service Evaluation

Mr Jamie Pitcairn,
R&D Manager
The State Hospital

18th December 2012

Dear Jamie,

Subject: Major Amendment
Re: Research proposal for the study; “A Randomised Controlled Trial of Computer Assisted Remediation in MDOs”.

Further to our initiation of the above study on Arran hub I write to provide the Research Committee with both a progress report, attached, and a proposal to amend our approach to that of a service evaluation rather than a research project.

A full outline of our progress to date is provided but, suffice to say, we have encountered a range of difficulties that have led us to conclude that a research project of the standard we had aspired to, with either a control group or control period, appears unlikely to succeed in The State Hospital at this time.

Given that at the end of the current project, (end January 2013) we will still have more than a year of product licence remaining we are keen that this be put to good use. Our suggestion is that CACR becomes part of the hospital's current menu of treatments and that a simple service evaluation is undertaken to provide some evidence with regard to its efficacy.

As a standard hospital treatment referrals would be invited from suitable patients. Patients would be asked if they would like to participate as they would for any other treatment to which they are referred but would not be asked to provide written consent. There would be no control period or additional assessments to identify if patients' current functioning is stable. Patients agreeing to participate in treatment would be asked to complete assessment measures before and afterwards and at fixed time points subsequently, as they would for other psychological therapies, to evaluate their personal progress. The assessments will be same as, or reduced in number, those identified as suitable during our original proposal as these are also most suitable for identifying individual progress. The treatment provided will be similar to that suggested in our previous proposal and conducted either on the wards as currently or perhaps in the learning centre (discussions are due to take place in January). Should sufficient data be collected a service evaluation will attempt to identify whether the treatment successfully improved patient function and whether

any gains were sustained. With appropriate permissions, routinely collected data could also form part of these analyses.

Although we acknowledge that as a service evaluation the methodology is far less robust than we would have hoped we still anticipate the results forming part of postgraduate theses for the University of Edinburgh.

Kind regards

Dr Suzanne O'Rourke

Email from the State Hospital R&D Manager confirming approval of service evaluation

From: Pitcairn Jamie (STATE HOSPITALS BOARD FOR SCOTLAND)
Sent: 29 April 2013 11:28
To: Alcock Duncan (STATE HOSPITALS BOARD FOR SCOTLAND); Gallagher Martin (NHS Lothian)
Subject: RE: Caldicott Approval

Dear Duncan, Martin,

I have had a quick look back over the paperwork for this study. The study was originally approved without the inclusion of the additional use of routinely collected data. However the study lead Dr Suzanne O'Rourke did submit a letter of amendment to the research committee indicating that there was a desire to utilise routinely collected clinical data to assist in the evaluation of the efficacy of the CACR pilot programme. The amendment was noted by the Research Committee and the need for caldicott guardian approval for the use of routine data reiterated, although I should say that Dr O'Rourke had made clear the intention to seek Caldicott approval. So in that sense the TSH Research Committee are satisfied that the research approval aspects have already been addressed, but that Caldicott Guardian approval should be sought for the additional use of clinical data collected for the purpose of ongoing care and treatment.

I hope this sounds reasonable Duncan, and perhaps I need to copy you into any future correspondence that recommends (or requires) that the Caldicott guardian should be approached, as standard practice. If you have any queries on this at all then please just get back to me.

Many Thanks

Jamie

Jamie Pitcairn

R&D Manager

The State Hospital

01555 840293 Ext: 4355

Email from the State Hospital Caldicott Guardian confirming approval

From: Gallagher Martin (NHS Lothian)
Sent: 20 May 2013 16:48
To: Alcock Duncan (STATE HOSPITALS BOARD FOR SCOTLAND)
Subject: RE: Caldicott Approval

Hi Duncan,

Thanks very much for this. I can confirm that it will only be myself and Suzanne that will have the list that matches the patients to the ID numbers.

Thanks,
Martin

From: Alcock Duncan (STATE HOSPITALS BOARD FOR SCOTLAND)
Sent: 10 May 2013 16:18
To: Gallagher Martin (NHS Lothian)
Cc: O'Rourke Suzanne (STATE HOSPITALS BOARD FOR SCOTLAND)
Subject: RE: Caldicott Approval

Hi Martin

This addresses any concerns I may have had. Only one further thing comes to mind and that is who will hold to list that matches the patients to the identification number. If this is only you and Suzanne then I am happy for you to proceed from a Caldicott standpoint.

Regards

Duncan

Dr Duncan Alcock

Consultant Forensic Psychiatrist/ Joint Associate Medical Director/
Caldicott Guardian/ Lewis Hub Clinical Lead

The State Hospital

Clinical/ Lewis Hub Matters Tel 01555 842044

Managerial/ Caldicott Matters Tel 01555 842221

From: Gallagher Martin (NHS Lothian)
Sent: 10 May 2013 10:00
To: Alcock Duncan (STATE HOSPITALS BOARD FOR SCOTLAND)
Subject: RE: Caldicott Approval

Hi Duncan,

Below is an amended version of the parts of my uni ethics form that relate to information governance. Please let me know if there is any other information you need and I will pass this on.

Thanks for your help,

Martin

How will the confidentiality of data, including the identity of participants (whether specifically recruited for the research or not) be ensured?

All assessments form part of patients' clinical records and will be stored on RiO, The State Hospital's electronic record system.

No identifiable information will be stored on the database created for the analysis of data (see below for details). All patients will be assigned an identification number for the purposes of the evaluation to ensure that all data stored on this database remains anonymous.

Who will be entitled to have access to the raw data?

As this is a service evaluation and the assessments form part of patients' clinical record, the data can be accessed by anyone at The State Hospital involved in the patients' care and treatment, with the exception of neuropsychology data which will only be accessible to psychology staff involved in their care and treatment.

Data will also be available to Martin Gallagher (Trainee Clinical Psychologist), Dr Suzanne O'Rourke (Consultant Forensic Clinical Neuropsychologist) and James Hartley to allow this to be analysed as part of the service evaluation. James Hartley is an Edinburgh University research student who has an honorary contract with The State Hospital and will be involved in evaluating the service. Mr Hartley will only have access to anonymised data.

What process will be used to access existing data?

PECC, CORE, BEST and DATIX information will be accessed by Martin Gallagher via The State Hospital's records. This information will then be fully anonymised and stored in the database (see below).

How and where will the data be stored, in what format, and for how long?

Data will be stored in two locations:

1. In accordance with standard practice within the hospital, raw data will be stored on RiO, the hospital's electronic record system,

to allow relevant clinical staff to access the information. This will take the form of electronic scans of recording forms for the various measures. This data will remain part of the clients' medical records.

2. Fully anonymised data will also be stored in a database located on a shared, secure drive within The State Hospital network. This will allow the information to be analysed as part of the service evaluation. Data will be stored for 10 years in accordance with relevant guidelines.

What steps have been taken to ensure that only entitled persons will have access to the data?

The State Hospital's information security policies and procedures ensure that access to patients' records via RiO is only granted to individuals within the hospital who have a genuine need to view the information.

IT have ensured that the shared network drive is only accessible to individuals directly involved in delivering and evaluating the treatment. This drive is not accessible outwith The State Hospital.

How will the data be disposed of?

The anonymised data stored on the shared drive will be deleted after 10 years, in accordance with the relevant guidelines.

How will the results of the research be used?

The results of the study will be used to evaluate the efficacy and feasibility of computer assisted cognitive remediation (CACR) within a high secure forensic hospital. This will help management staff within the hospital to decide whether or not to invest further in CACR as part of the available treatments within the hospital.

It is anticipated that the results will also be published in a relevant journal and form part of the doctoral theses of Martin Gallagher and James Hartley.

From: Alcock Duncan (STATE HOSPITALS BOARD FOR SCOTLAND)
Sent: 30 April 2013 10:34
To: Gallagher Martin (NHS Lothian); Pitcairn Jamie (STATE HOSPITALS BOARD FOR SCOTLAND)
Subject: RE: Caldicott Approval

Thanks Jamie/Martin

All would I need in this instance is something in writing documenting the Information Governance safeguards that will be in place for this project. In particular how you will protect the confidential patient information that will be collected for this project. It is likely this was previously covered in the original research proposal so it shouldn't require you to start from scratch. Suzanne will be able to provide assistance with this if needs be as the study Lead.

Regards

Duncan

Dr Duncan Alcock

Joint Associate Medical Director/Consultant Forensic
Psychiatrist/Caldicott Guardian

The State Hospital, Carstairs

Tel 01555 842044/842221

From: Gallagher Martin (NHS Lothian)
Sent: 29 April 2013 11:36
To: Pitcairn Jamie (STATE HOSPITALS BOARD FOR SCOTLAND); Alcock
Duncan (STATE HOSPITALS BOARD FOR SCOTLAND)
Subject: RE: Caldicott Approval

Dear Jamie, Duncan,

Many thanks for your replies.

Duncan, if there is any information that you require for this then please let me know.

Thanks for your help,
Martin

From: Pitcairn Jamie (STATE HOSPITALS BOARD FOR SCOTLAND)
Sent: 29 April 2013 11:28
To: Alcock Duncan (STATE HOSPITALS BOARD FOR SCOTLAND); Gallagher
Martin (NHS Lothian)
Subject: RE: Caldicott Approval

Dear Duncan, Martin,

I have had a quick look back over the paperwork for this study. The study was originally approved without the inclusion of the additional use of routinely collected data. However the study lead

Dr Suzanne O'Rourke did submit a letter of amendment to the research committee indicating that there was a desire to utilise routinely collected clinical data to assist in the evaluation of the efficacy of the CACR pilot programme. The amendment was noted by the Research Committee and the need for caldicott guardian approval for the use of routine data reiterated, although I should say that Dr O'Rourke had made clear the intention to seek Caldicott approval. So in that sense the TSH Research Committee are satisfied that the research approval aspects have already been addressed, but that Caldicott Guardian approval should be sought for the additional use of clinical data collected for the purpose of ongoing care and treatment.

I hope this sounds reasonable Duncan, and perhaps I need to copy you into any future correspondence that recommends (or requires) that the Caldicott guardian should be approached, as standard practice. If you have any queries on this at all then please just get back to me.

Many Thanks

Jamie

Jamie Pitcairn

R&D Manager

The State Hospital

01555 840293 Ext: 4355

From: Alcock Duncan (STATE HOSPITALS BOARD FOR SCOTLAND)
Sent: 25 April 2013 16:44
To: Gallagher Martin (NHS Lothian)
Cc: Pitcairn Jamie (STATE HOSPITALS BOARD FOR SCOTLAND)
Subject: RE: Caldicott Approval

Hi Martin

It would appear to me that what you are suggesting is a new piece of research in relation to the cognitive remediation therapy that is occurring in the hospital. As a first point I would suggest running this past Jamie Pitcairn (Research and Development Manager) to get his views on whether this needs to go in front of the Research Committee.

Regards

Duncan

Dr Duncan Alcock

Consultant Forensic Psychiatrist/ Joint Associate Medical Director/
Caldicott Guardian/ Lewis Hub Clinical Lead

The State Hospital

Clinical/ Lewis Hub Matters Tel 01555 842044

Managerial/ Caldicott Matters Tel 01555 842221

From: Gallagher Martin (NHS Lothian)
Sent: 08 April 2013 13:16
To: Alcock Duncan (STATE HOSPITALS BOARD FOR SCOTLAND)
Subject: Caldicott Approval

Dear Dr Alcock,

As part of my training in clinical psychology, I am completing a research project that is looking at the efficacy of computer assisted cognitive remediation therapy. We are hoping to use the data from patients' existing PECC assessments to inform our analysis of psychotic symptoms. I understand I will require Caldicott approval for this.

I am wondering if there is a standard procedure/application form for applying for approval? If it would be helpful I can forward on my research proposal document.

Thanks for your help,

Martin

Martin Gallagher

Trainee Clinical Psychologist